

US3742034 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

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US3742034

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

[Participant ID](#)

US3742034

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

US3742034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN OCT 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:34
Height (xxx.x)	64.7 in
Weight (xxx.x)	157.5 lb
BMI (xxx.x)	26.50830 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:00:28

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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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	25 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:00:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 108509

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Height	64.7 in
Weight	157.5 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Height	64.7 in
Weight	157.5 lb
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	18:06 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 18:06
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Height	64.7 in
Weight	157.5 lb
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	20:30 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 20:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 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: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:00:28

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 AUG 2020

What was the treatment time? (00:00-23:59) 20:00 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 20:00

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	17:25 (24 HR)
Collection date and time (derived)	25 AUG 2020 17:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:40	25 AUG 2020 17:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

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: 10 Jun 2021 09:29:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:31

PC Open Date & Time

25 AUG 2020 20:20

PC Close Date & Time

25 AUG 2020 22:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	26 AUG 2020 00:06
PC Open Date & Time	25 AUG 2020 23:45
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:38

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 17:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

29 AUG 2020 12:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 20:32

PC Open Date & Time

25 AUG 2020 20:20

PC Close Date & Time

25 AUG 2020 22:50

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

26 AUG 2020 00:06

PC Open Date & Time

25 AUG 2020 23:45

PC Close Date & Time

26 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:03

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 17:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

31 AUG 2020 20:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 20:32
PC Open Date & Time	25 AUG 2020 20:20
PC Close Date & Time	25 AUG 2020 22:50

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 00:07
PC Open Date & Time	25 AUG 2020 23:45
PC Close Date & Time	26 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:02
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 17:16
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:19
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

53 of 2117

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2117

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:26
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3742034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:27

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:10
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	067 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	17:13 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 17:13
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG

US3742034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	22 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 16:42 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 16:42

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

US3742034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	15:31 (24 HR)
Collection date and time (derived)	22 SEP 2020 15:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:31	22 SEP 2020 15:31
Nasopharyngeal Swab 2	No		

US3742034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 22 SEP 2020 17:14

PC Open Date & Time 22 SEP 2020 17:02

PC Close Date & Time 22 SEP 2020 19:32

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

PC Time Stamp	22 SEP 2020 21:00
PC Open Date & Time	22 SEP 2020 20:27
PC Close Date & Time	23 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 12:51

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:04

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 00:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 23:31

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

22 SEP 2020 17:14

PC Open Date & Time

22 SEP 2020 17:02

PC Close Date & Time

22 SEP 2020 19:32

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

22 SEP 2020 20:59

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

24 SEP 2020 12:50

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

25 SEP 2020 18:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

26 SEP 2020 12:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

28 SEP 2020 00:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

28 SEP 2020 23:32

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 17:15
PC Open Date & Time	22 SEP 2020 17:02
PC Close Date & Time	22 SEP 2020 19:32

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 20:59
PC Open Date & Time	22 SEP 2020 20:27
PC Close Date & Time	23 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:42
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 00:17
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

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 ☒

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 23:32
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3742034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3742034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	15:17 (24 HR)
Collection date and time (derived)	20 OCT 2020 15:17

US3742034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:00:28

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 12:01:09
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

01 NOV 2020 00:02:02

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

08 NOV 2020 08:53:35

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
-----------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

07 DEC 2020 13:54:28

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 10:12:28
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

17 DEC 2020 02:02:40

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

24 DEC 2020 00:41:01

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

31 DEC 2020 00:53:10

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

07 JAN 2021 00:36:14

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 08:50:22
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 05:31:11
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

28 JAN 2021 11:50:18

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

04 FEB 2021 04:47:09

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 FEB 2021 03:10:03
Patient Cloud Open Date & Time	11 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
132 of 2117	

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

18 FEB 2021 07:28:28

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

25 FEB 2021 05:42:35

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

04 MAR 2021 09:54:17

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

11 MAR 2021 05:46:35

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

18 MAR 2021 04:53:08

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

25 MAR 2021 08:36:02

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

01 APR 2021 09:55:36

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

08 APR 2021 05:30:29

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

15 APR 2021 05:00:53

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

22 APR 2021 05:37:30

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Date and time of submission

29 APR 2021 05:09:40

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 JUL 2021 00:01
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Patient Cloud Close Date & Time	19 JUL 2021 23:59
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US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
-----------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3742034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:29:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 19:52:28

US3742034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:35:06

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:35:06

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 20:56:35

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 20:56:35

Generated On: 10 Jun 2021 09:29:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 20:56:35

Generated On: 10 Jun 2021 09:29:49

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.

US3742034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:36:26

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	15:05 (24 HR)
Collection date and time (derived)	23 MAR 2021 15:05

US3742034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 20:56:35

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742034

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742034

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:49

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3742034

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:29:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 19:21:04

Generated On: 10 Jun 2021 09:29:49

Date of updated informed consent (dd MMM yyyy) 07 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 7 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00-23:59)	15:21 (24 HR)
Collection date and time (derived)	7 JAN 2021 15:21

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	15:24
Collection Date and Time (derived)	7 JAN 2021 15:24

US3742034

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

AEID

Adverse event

HEADACHE

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)

7 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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)	_____

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

AEID	USA-US127-2021-MRNA-1273-P30 1000011
Adverse event	RUPTURED APPENDIX
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	23 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT WAS FOLLOWED UP DURING A SAFETY CALL AND REPORTED SHE HAD AN EMERGENCY SURGERY FOR RUPTURED APPENDIX. SHE VOLUNTEERED SHE IS CURRENTLY DISCHARGED AS OF 23 FEB 2021
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 16:31:49

Generated On: 10 Jun 2021 09:29:49

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

Yes ☒

No ☐

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

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication ZESTORETIC

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 20/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication	FISH OIL
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SUPPLEMENT GENERAL HEALTH
Dose per administration	1200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT/GENERAL
WELLNESS

Dose per administration 2000

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)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 65

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 (5)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500

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)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication RUPTURED APPENDIX

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify UNKNOWN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:11:13

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Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication RUPTURED APPENDIX

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify UNKNOWN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication CEFTIN

Prophylaxis Yes ☐
No ☒

Indication RUPTURED APPENDIX

Dose per administration 500

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 (11)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication RUPTURED APPENDIX

Dose per administration 500

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 (12)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication RUPTURED APPENDIX

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify UNKNOWN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

Name of Medication SHINGRIX VACCINE

Prophylaxis Yes ☒
No ☐

Indication ZOSTER PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:11:13

Generated On: 10 Jun 2021 09:29:49

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:48:40

Generated On: 10 Jun 2021 09:29:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:48:40

Generated On: 10 Jun 2021 09:29:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	LAPAROSCOPIC APPENDECTOMY	Other	APPENDICITIS

US3742034

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:29:49

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

US3742034

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:29:49

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 ☐

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:24
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:10
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/MAR/2021 12:53
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	09/MAR/2021 12:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/APR/2021 14:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/APR/2021 09:28
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/APR/2021 09:33
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	21/APR/2021 12:09
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

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 23:34:06

Generated On: 10 Jun 2021 09:29:49

SAEID	USA-US127-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	28/APR/2021 12:23
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

US3742034 (Prod: University of Maryland School of Medicine)

US3742034

Form: Participant Creation

Generated On: 10 Jun 2021 09:29:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'US3742034'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:59:26

US3742034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	21 Aug 2020 19:41:31

US3742034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:59:27

US3742034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	21 Aug 2020 19:41:31

US3742034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'SCRN'	System	21 Aug 2020 19:41:31

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:59:28

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '49'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'YEARS'	System	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '49'	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Female (F)'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'I'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	Hassan Haji (b) (4)	21 Aug 2020 19:42:58

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'Aug 2020'	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '2020'	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:59:27

US3742034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'I'	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 12:28:47

US3742034

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:29:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:42:00

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Aug 2020 11:43:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 11:43:48
Data point term sent to Coder	(b) (4)	26 Aug 2020 11:42:37
User entered 'High Blood Pressure'	System (b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'UN Oct 2018' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:25:46
User entered '31 Oct 2018'	(b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'Oct 2018'	System	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '2018'	System	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered empty.	System	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered empty.	System	26 Aug 2020 11:42:25

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 11:49:48
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 11:49:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 11:46:43
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '11:34' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '18:06'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '21 Aug 2020 11:34'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:49:48
User entered '25 Aug 2020 18:06'	System	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '64.7' in reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 11:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 11:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 11:46:43
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:46:43
DataPoint set to visible.	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '157.5' lb reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 11:49:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 11:49:48
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 11:46:43
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:46:43
DataPoint set to visible.	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
Amendment Manager: User entered '26.50830'	System	17 Sep 2020 00:18:03
User entered '26.5'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:46:43
DataPoint set to visible.	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'kg/m2'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:46:43
DataPoint set to visible.	System	25 Aug 2020 23:47:25

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '97.8' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '98.2' F	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '47' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '67'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'bpm'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:49:48
User entered 'bpm'	System	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '14'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'breaths/min'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:49:48
User entered 'breaths/min'	System	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '122' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '124'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'mmHg'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:49:48
User entered 'mmHg'	System	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '71' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:49:48
User entered '68'	(b) (4), (b) (6)	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'mmHg'	System	26 Aug 2020 11:52:55
User entered empty.	System	26 Aug 2020 11:49:48
User entered 'mmHg'	System	26 Aug 2020 11:46:43

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00

US3742034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00

US3742034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:50:18

US3742034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:50:18

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:49

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:17

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered empty.	System	26 Aug 2020 11:43:52

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 00:09:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 00:09:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 00:09:45
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 00:09:35
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 00:09:35

US3742034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 12:23:42

US3742034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.'	System	26 Aug 2020 00:10:24
answered by data change (Site from System).		
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.'	System	26 Aug 2020 00:10:24
answered by data change (Site from System).		
User entered '25 Aug 2020' reason for change: Data Entry Error	Toni Robinson (b) (4)	26 Aug 2020 00:10:24
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
User entered '21 Aug 2020'	System	26 Aug 2020 00:06:52
	Sherry McCammon (b) (4)	25 Aug 2020 12:23:42
	(b) (4)	

US3742034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	25 Aug 2020 12:23:42

US3742034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'VISIT1'	System	25 Aug 2020 12:23:42

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 00:10:24
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 00:10:24
User entered '25 AUG 2020'	System	25 Aug 2020 23:14:23
	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 23:14:23

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '108509'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 23:14:23

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 23:14:23

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:55:24

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:55:24

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:55:24

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:55:24

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:55:24

US3742034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	Sherry McCammon (b) (4)	27 Oct 2020 20:15:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 01:58:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:58:34

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '64.7' in reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '157.5' lb reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '64.7' in reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '157.5' lb reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '18:06' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '11:34'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '25 Aug 2020 18:06'	System	26 Aug 2020 11:54:42
User entered '25 Aug 2020 11:34'	System	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '98.2' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '97.8' F	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '67' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '47'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'bpm'	System	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '16'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'breaths/min'	System	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '124' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '122'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered '71'	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '64.7' in reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '157.5' lb reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 11:54:42
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 11:51:38

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '20:30'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '25 Aug 2020 20:30'	System	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '58'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'bpm'	System	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'breaths/min'	System	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '129'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '76'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	26 Aug 2020 11:56:31

US3742034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:50:46

US3742034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:50:46

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:45:34
Query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'UPDATED TO REMOVE DUPLICATE ENTRY. SECOND TEST NOT REQUIRED' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:41:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:41:31
User opened query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:45:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:41:31
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:41:31
User entered 'Urine (URINE)'	(b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:41:31
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:05:34
Query 'per CDM: please input yes or no in this field' answered with 'NOT COLLECTED' (Site from DM).	Kaitlin Mason (b) (4)	12 Oct 2020 13:09:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	12 Oct 2020 13:09:14
	(b) (4)	
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 13:44:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:41:31
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered empty.	System	26 Aug 2020 11:44:31

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Toni Robinson (b) (4)	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Toni Robinson (b) (4)	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Toni Robinson (b) (4)	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Aug 2020 00:10:24
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 00:10:24
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 00:06:52
User entered '25 Aug 2020'	Toni Robinson (b) (4)	26 Aug 2020 00:06:52
	(b) (4)	

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '20:00'	Toni Robinson (b) (4)	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '25 Aug 2020 20:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'ONCE'	System	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 00:06:52

US3742034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:44:49

US3742034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:44:49

US3742034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '17:25'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:44:49

US3742034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '25 Aug 2020 17:25'	System	26 Aug 2020 11:44:49

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '17:40'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '25 Aug 2020 17:40'	System	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered empty.	System	26 Aug 2020 11:45:01

US3742034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 11:56:54

US3742034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '1'	System	26 Aug 2020 11:56:54

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:31:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8655cdb6-9251-4dda-85d7-122193cbdb6a' User entered 'Yes (Y)'	System	26 Aug 2020 00:32:01
	System	26 Aug 2020 00:32:01

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:31:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8655cdb6-9251-4dda-85d7-122193cbdb6a' User entered '97.8'	System	26 Aug 2020 00:32:01
	System	26 Aug 2020 00:32:01

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:31:54', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8655cdb6-9251-4dda-85d7-122193cbdb6a'	System	26 Aug 2020 00:32:01
User entered 'No (N)'	System	26 Aug 2020 00:32:01

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:31:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8655cdb6-9251-4dda-85d7-122193cbdb6a' User entered '25 Aug 2020 20:31'	System	26 Aug 2020 00:32:01
	System	26 Aug 2020 00:32:01

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 20:20'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 22:50'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '226c1a2e-9c3a-49ff-b26d-9c32496aa406'	System	26 Aug 2020 04:06:21
User entered 'Yes (Y)'	System	26 Aug 2020 04:06:21

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:09', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '226c1a2e-9c3a-49ff-b26d-9c32496aa406' User entered '97.2'	System	26 Aug 2020 04:06:21
	System	26 Aug 2020 04:06:21

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '226c1a2e-9c3a-49ff-b26d-9c32496aa406'	System	26 Aug 2020 04:06:21
User entered 'No (N)'	System	26 Aug 2020 04:06:21

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '226c1a2e-9c3a-49ff-b26d-9c32496aa406'	System	26 Aug 2020 04:06:21
User entered '26 Aug 2020 00:06'	System	26 Aug 2020 04:06:21

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 23:45'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 2'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:38:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '941c7630-c0b3-4442-927b-9fef4e7dcd58'	System	26 Aug 2020 16:38:25
User entered 'Yes (Y)'	System	26 Aug 2020 16:38:25

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:38:12', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '941c7630-c0b3-4442-927b-9fef4e7dcd58' User entered '97.7'	System	26 Aug 2020 16:38:25
	System	26 Aug 2020 16:38:25

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:38:16', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '941c7630-c0b3-4442-927b-9fef4e7dcd58'	System	26 Aug 2020 16:38:25
User entered 'No (N)'	System	26 Aug 2020 16:38:25

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:38:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '941c7630-c0b3-4442-927b-9fef4e7dcd58'	System	26 Aug 2020 16:38:25
User entered '26 Aug 2020 12:38'	System	26 Aug 2020 16:38:25

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 3'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b690e6d3-afe8-471e-b5c3-21243e5271a1' User entered 'Yes (Y)'	System	27 Aug 2020 16:01:30
	System	27 Aug 2020 16:01:30

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b690e6d3-afe8-471e-b5c3-21243e5271a1' User entered '97.0'	System	27 Aug 2020 16:01:30
	System	27 Aug 2020 16:01:30

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:16', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b690e6d3-afe8-471e-b5c3-21243e5271a1'	System	27 Aug 2020 16:01:30
User entered 'No (N)'	System	27 Aug 2020 16:01:30

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b690e6d3-afe8-471e-b5c3-21243e5271a1' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:30
	System	27 Aug 2020 16:01:30

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 4'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:08', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '65bf7174-9cb7-491a-8b79-157c64484af1' User entered 'Yes (Y)'	System	28 Aug 2020 21:17:24
	System	28 Aug 2020 21:17:24

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '65bf7174-9cb7-491a-8b79-157c64484af1' User entered '98.3'	System	28 Aug 2020 21:17:24
	System	28 Aug 2020 21:17:24

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '65bf7174-9cb7-491a-8b79-157c64484af1'	System	28 Aug 2020 21:17:24
User entered 'No (N)'	System	28 Aug 2020 21:17:24

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '65bf7174-9cb7-491a-8b79-157c64484af1' User entered '28 Aug 2020 17:17'	System	28 Aug 2020 21:17:24
	System	28 Aug 2020 21:17:24

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 5'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4353c2b9-d410-4cbf-8664-97d86171a955'	System	29 Aug 2020 16:20:16
User entered 'Yes (Y)'	System	29 Aug 2020 16:20:16

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4353c2b9-d410-4cbf-8664-97d86171a955'	System	29 Aug 2020 16:20:16
User entered '96.6'	System	29 Aug 2020 16:20:16

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4353c2b9-d410-4cbf-8664-97d86171a955'	System	29 Aug 2020 16:20:16
User entered 'No (N)'	System	29 Aug 2020 16:20:16

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4353c2b9-d410-4cbf-8664-97d86171a955'	System	29 Aug 2020 16:20:16
User entered '29 Aug 2020 12:20'	System	29 Aug 2020 16:20:16

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 6'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:00:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f221a533-2f38-4741-acb5-5f07973ad690' User entered 'Yes (Y)'	System	30 Aug 2020 16:01:22
	System	30 Aug 2020 16:01:22

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:00:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f221a533-2f38-4741-acb5-5f07973ad690' User entered '96.9'	System	30 Aug 2020 16:01:22
	System	30 Aug 2020 16:01:22

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f221a533-2f38-4741-acb5-5f07973ad690'	System	30 Aug 2020 16:01:22
User entered 'No (N)'	System	30 Aug 2020 16:01:22

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f221a533-2f38-4741-acb5-5f07973ad690' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:01:22
	System	30 Aug 2020 16:01:22

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 7'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:24:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a047c5f6-9dc0-4f25-b919-db0170d82bdd' User entered 'Yes (Y)'	System	01 Sep 2020 00:25:18
	System	01 Sep 2020 00:25:18

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a047c5f6-9dc0-4f25-b919-db0170d82bdd' User entered '97.5'	System	01 Sep 2020 00:25:18
	System	01 Sep 2020 00:25:18

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:12', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a047c5f6-9dc0-4f25-b919-db0170d82bdd' User entered 'No (N)'	System	01 Sep 2020 00:25:18
	System	01 Sep 2020 00:25:18

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:15', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a047c5f6-9dc0-4f25-b919-db0170d82bdd' User entered '31 Aug 2020 20:25'	System	01 Sep 2020 00:25:18
	System	01 Sep 2020 00:25:18

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c8943b3d-a729-4cd2-a7f9-374ab89d2d2e' User entered 'None (1)'	System	26 Aug 2020 00:32:37
	System	26 Aug 2020 00:32:37

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c8943b3d-a729-4cd2-a7f9-374ab89d2d2e' User entered 'No (N)'	System	26 Aug 2020 00:32:37
	System	26 Aug 2020 00:32:37

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c8943b3d-a729-4cd2-a7f9-374ab89d2d2e' User entered 'No (N)'	System	26 Aug 2020 00:32:37
	System	26 Aug 2020 00:32:37

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:31', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c8943b3d-a729-4cd2-a7f9-374ab89d2d2e' User entered 'None (1)'	System	26 Aug 2020 00:32:37
	System	26 Aug 2020 00:32:37

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:35', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c8943b3d-a729-4cd2-a7f9-374ab89d2d2e' User entered '25 Aug 2020 20:32'	System	26 Aug 2020 00:32:37
	System	26 Aug 2020 00:32:37

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 20:20'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 22:50'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:24', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '30e09ad1-b398-42da-b1dc-e8792dcbe081' User entered 'None (1)'	System	26 Aug 2020 04:06:43
	System	26 Aug 2020 04:06:43

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:27', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '30e09ad1-b398-42da-b1dc-e8792dcbe081' User entered 'No (N)'	System	26 Aug 2020 04:06:43
	System	26 Aug 2020 04:06:43

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:30', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '30e09ad1-b398-42da-b1dc-e8792dcbe081' User entered 'No (N)'	System	26 Aug 2020 04:06:43
	System	26 Aug 2020 04:06:43

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:34', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '30e09ad1-b398-42da-b1dc-e8792dcbe081' User entered 'None (1)'	System	26 Aug 2020 04:06:43
	System	26 Aug 2020 04:06:43

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '30e09ad1-b398-42da-b1dc-e8792dcbe081' User entered '26 Aug 2020 00:06'	System	26 Aug 2020 04:06:43
	System	26 Aug 2020 04:06:43

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 23:45'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 2'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:32', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b87441ce-2d43-45fd-8f17-4eac9953e991'	System	26 Aug 2020 16:03:58
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 16:03:58

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:38', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b87441ce-2d43-45fd-8f17-4eac9953e991'	System	26 Aug 2020 16:03:58
User entered 'No (N)'	System	26 Aug 2020 16:03:58

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:42', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b87441ce-2d43-45fd-8f17-4eac9953e991'	System	26 Aug 2020 16:03:58
User entered 'No (N)'	System	26 Aug 2020 16:03:58

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b87441ce-2d43-45fd-8f17-4eac9953e991' User entered 'None (1)'	System	26 Aug 2020 16:03:58
	System	26 Aug 2020 16:03:58

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b87441ce-2d43-45fd-8f17-4eac9953e991' User entered '26 Aug 2020 12:03'	System	26 Aug 2020 16:03:58
	System	26 Aug 2020 16:03:58

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 3'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b2cfd3ad-b879-466d-9e23-a08afda2aea4'	System	27 Aug 2020 16:01:54
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 16:01:54

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:26', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b2cfd3ad-b879-466d-9e23-a08afda2aea4'	System	27 Aug 2020 16:01:54
User entered 'No (N)'	System	27 Aug 2020 16:01:54

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:29', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b2cfd3ad-b879-466d-9e23-a08afda2aea4'	System	27 Aug 2020 16:01:54
User entered 'No (N)'	System	27 Aug 2020 16:01:54

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:36', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b2cfd3ad-b879-466d-9e23-a08afda2aea4'	System	27 Aug 2020 16:01:54
User entered 'None (1)'	System	27 Aug 2020 16:01:54

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b2cfd3ad-b879-466d-9e23-a08afda2aea4' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:54
	System	27 Aug 2020 16:01:54

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 4'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:53', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8ffcc859-aa7f-4433-b716-21c9f9d5edbd'	System	28 Aug 2020 21:17:05
User entered 'None (1)'	System	28 Aug 2020 21:17:05

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8ffcc859-aa7f-4433-b716-21c9f9d5edbd'	System	28 Aug 2020 21:17:05
User entered 'No (N)'	System	28 Aug 2020 21:17:05

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8ffcc859-aa7f-4433-b716-21c9f9d5edbd'	System	28 Aug 2020 21:17:05
User entered 'No (N)'	System	28 Aug 2020 21:17:05

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8ffcc859-aa7f-4433-b716-21c9f9d5edbd' User entered 'None (1)'	System	28 Aug 2020 21:17:05
	System	28 Aug 2020 21:17:05

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:17:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8ffcc859-aa7f-4433-b716-21c9f9d5edbd' User entered '28 Aug 2020 17:17'	System	28 Aug 2020 21:17:05
	System	28 Aug 2020 21:17:05

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 5'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:16', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '938877c6-ca17-4a7f-b164-a1ffa9eee48d' User entered 'None (1)'	System	29 Aug 2020 16:20:31
	System	29 Aug 2020 16:20:31

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '938877c6-ca17-4a7f-b164-a1ffa9eee48d' User entered 'No (N)'	System	29 Aug 2020 16:20:31
	System	29 Aug 2020 16:20:31

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:22', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '938877c6-ca17-4a7f-b164-a1ffa9eee48d' User entered 'No (N)'	System	29 Aug 2020 16:20:31
	System	29 Aug 2020 16:20:31

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:24', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '938877c6-ca17-4a7f-b164-a1ffa9eee48d' User entered 'None (1)'	System	29 Aug 2020 16:20:31
	System	29 Aug 2020 16:20:31

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:20:29', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '938877c6-ca17-4a7f-b164-a1ffa9eee48d' User entered '29 Aug 2020 12:20'	System	29 Aug 2020 16:20:31
	System	29 Aug 2020 16:20:31

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 6'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:12', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0f89d1c2-d9bb-474b-8255-b5e1ecf8083e' User entered 'None (1)'	System	30 Aug 2020 16:01:55
	System	30 Aug 2020 16:01:55

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0f89d1c2-d9bb-474b-8255-b5e1ecf8083e' User entered 'No (N)'	System	30 Aug 2020 16:01:55
	System	30 Aug 2020 16:01:55

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0f89d1c2-d9bb-474b-8255-b5e1ecf8083e' User entered 'No (N)'	System	30 Aug 2020 16:01:55
	System	30 Aug 2020 16:01:55

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0f89d1c2-d9bb-474b-8255-b5e1ecf8083e' User entered 'None (1)'	System	30 Aug 2020 16:01:55
	System	30 Aug 2020 16:01:55

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:24', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0f89d1c2-d9bb-474b-8255-b5e1ecf8083e' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:01:55
	System	30 Aug 2020 16:01:55

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 7'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1606863c-2651-4ffc-a872-bbcbfea16db8'	System	01 Sep 2020 00:25:38
User entered 'None (1)'	System	01 Sep 2020 00:25:38

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:26', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1606863c-2651-4ffc-a872-bbcbfea16db8'	System	01 Sep 2020 00:25:38
User entered 'No (N)'	System	01 Sep 2020 00:25:38

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:29', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1606863c-2651-4ffc-a872-bbcbfea16db8' User entered 'No (N)'	System	01 Sep 2020 00:25:38
	System	01 Sep 2020 00:25:38

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:32', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1606863c-2651-4ffc-a872-bbcbfea16db8'	System	01 Sep 2020 00:25:38
User entered 'None (1)'	System	01 Sep 2020 00:25:38

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:35', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1606863c-2651-4ffc-a872-bbcbfea16db8' User entered '31 Aug 2020 20:25'	System	01 Sep 2020 00:25:38
	System	01 Sep 2020 00:25:38

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:42', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:48', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5' User entered 'None (0)'	System	26 Aug 2020 00:33:00
	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5'	System	26 Aug 2020 00:33:00
User entered 'No (N)'	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-25T20:32:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4025f665-46cc-4c28-956d-cb1205eacda5'	System	26 Aug 2020 00:33:00
User entered '25 Aug 2020 20:32'	System	26 Aug 2020 00:33:00

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 20:20'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 22:50'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:45', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:49', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:53', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:06:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'None (0)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:07:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered 'No (N)'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T00:07:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '66c816ac-c582-4679-b602-aa9db6d465f6' User entered '26 Aug 2020 00:07'	System	26 Aug 2020 04:07:09
	System	26 Aug 2020 04:07:09

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Aug 2020 23:45'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 2'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:02:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:02:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:02:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'None (0)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered 'No (N)'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-26T12:03:22', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '09c2cf6e-0a05-4a8a-b000-46e55a2e82ea' User entered '26 Aug 2020 12:03'	System	26 Aug 2020 16:03:37
	System	26 Aug 2020 16:03:37

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 3'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:49', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0'	System	27 Aug 2020 16:02:48
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered 'None (0)'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:01:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered 'None (0)'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:02:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered 'None (0)'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:02:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered 'None (0)'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:02:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered 'None (0)'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:02:12', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0'	System	27 Aug 2020 16:02:48
User entered 'No (N)'	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-27T12:02:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '4b4f89a7-757f-40f0-9b7c-64fecf8e21e0' User entered '27 Aug 2020 12:02'	System	27 Aug 2020 16:02:48
	System	27 Aug 2020 16:02:48

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 4'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:15:53', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3'	System	28 Aug 2020 21:16:45
User entered 'No interference with activity (1)'	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:24', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:37', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3'	System	28 Aug 2020 21:16:45
User entered 'No (N)'	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-28T17:16:43', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b94f2da7-babd-4d1c-9427-6cfa4e1ac9f3' User entered '28 Aug 2020 17:16'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 5'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:18:53', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977'	System	29 Aug 2020 16:19:36
User entered 'None (0)'	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:18:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered 'None (0)'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:18:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered 'None (0)'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:01', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered 'None (0)'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered 'None (0)'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:05', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered 'None (0)'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:16', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977'	System	29 Aug 2020 16:19:36
User entered 'No (N)'	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-29T12:19:34', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6e9595a1-1231-4a82-a3ad-7f6667172977' User entered '29 Aug 2020 12:19'	System	29 Aug 2020 16:19:36
	System	29 Aug 2020 16:19:36

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 6'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:35', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:37', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:49', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered 'None (0)'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:01:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14'	System	30 Aug 2020 16:02:40
User entered 'No (N)'	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-30T12:02:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b4babb7e-67eb-4f0e-8e91-c567f11c0c14' User entered '30 Aug 2020 12:02'	System	30 Aug 2020 16:02:40
	System	30 Aug 2020 16:02:40

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 7'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:41', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:44', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:48', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:25:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:26:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'None (0)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:26:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a' User entered 'No (N)'	System	01 Sep 2020 00:26:16
	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-08-31T20:26:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '45f44f49-f12a-48a5-9022-218b6513b49a'	System	01 Sep 2020 00:26:16
User entered '31 Aug 2020 20:26'	System	01 Sep 2020 00:26:16

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 00:06:52

US3742034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:18:00

US3742034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:18:00

US3742034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:18:00

US3742034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:18:00

US3742034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:13:49

US3742034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	02 Sep 2020 15:13:49

US3742034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:06:33

US3742034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:06:33

US3742034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:06:33

US3742034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:06:33

US3742034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 22:06:10

US3742034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	08 Sep 2020 22:06:10

US3742034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 13:53:59

US3742034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 13:53:59

US3742034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 13:53:59

US3742034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 13:53:59

US3742034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	Toni Robinson (b) (4)	22 Sep 2020 20:50:58

US3742034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	22 Sep 2020 20:50:58

US3742034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:41:45

US3742034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:41:45

US3742034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	29 Sep 2020 13:41:45

US3742034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'VISIT2'	System	29 Sep 2020 13:41:45

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43
	(b) (4)	

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '15:10'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '22 Sep 2020 15:10'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '098.2' F	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Other (Other)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'temporal'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '067'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'bpm'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '16'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'breaths/min'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '113'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '073'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '17:13'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '22 Sep 2020 17:13'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '097.8' F	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '062'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'bpm'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '14'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'breaths/min'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '132'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '082'	Sherry McCammon (b) (4)	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'mmHg'	System	29 Sep 2020 13:44:43

US3742034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:42:35

US3742034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:42:35

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Urine (URINE)'	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Negative (NEGATIVE)'	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered empty.	System	29 Sep 2020 13:46:02

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '16:42'	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '22 Sep 2020 16:42'	System	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'ONCE'	System	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 20:51:37

US3742034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:47

US3742034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:47

US3742034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '15:31'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:47

US3742034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '22 Sep 2020 15:31'	System	29 Sep 2020 13:45:47

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '15:31'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '22 Sep 2020 15:31'	System	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered empty.	System	29 Sep 2020 13:45:31

US3742034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 13:45:01

US3742034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '1'	System	29 Sep 2020 13:45:01

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:08', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c679c02f-733e-452f-ba5c-c66f3399d750'	System	22 Sep 2020 21:14:24
User entered 'Yes (Y)'	System	22 Sep 2020 21:14:24

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c679c02f-733e-452f-ba5c-c66f3399d750' User entered '97.8'	System	22 Sep 2020 21:14:24
	System	22 Sep 2020 21:14:24

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c679c02f-733e-452f-ba5c-c66f3399d750'	System	22 Sep 2020 21:14:24
User entered 'No (N)'	System	22 Sep 2020 21:14:24

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:21', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c679c02f-733e-452f-ba5c-c66f3399d750'	System	22 Sep 2020 21:14:24
User entered '22 Sep 2020 17:14'	System	22 Sep 2020 21:14:24

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:48', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8faa5da5-db8c-444a-8835-7ba1516ab1be' User entered 'Yes (Y)'	System	23 Sep 2020 01:00:08
	System	23 Sep 2020 01:00:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:54', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8faa5da5-db8c-444a-8835-7ba1516ab1be' User entered '96.9'	System	23 Sep 2020 01:00:08
	System	23 Sep 2020 01:00:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8faa5da5-db8c-444a-8835-7ba1516ab1be' User entered 'No (N)'	System	23 Sep 2020 01:00:08
	System	23 Sep 2020 01:00:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T21:00:01', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8faa5da5-db8c-444a-8835-7ba1516ab1be'	System	23 Sep 2020 01:00:08
User entered '22 Sep 2020 21:00'	System	23 Sep 2020 01:00:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 2'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '89e69916-d164-42db-b748-c4853d3b118e' User entered 'Yes (Y)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:21', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '89e69916-d164-42db-b748-c4853d3b118e' User entered '96.5'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:25', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '89e69916-d164-42db-b748-c4853d3b118e' User entered 'No (N)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:27', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '89e69916-d164-42db-b748-c4853d3b118e' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 3'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '428676a7-5d91-40e4-be29-9f7f3ff2dbbb'	System	24 Sep 2020 16:51:08
User entered 'Yes (Y)'	System	24 Sep 2020 16:51:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '428676a7-5d91-40e4-be29-9f7f3ff2dbbb' User entered '96.8'	System	24 Sep 2020 16:51:08
	System	24 Sep 2020 16:51:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '428676a7-5d91-40e4-be29-9f7f3ff2dbbb'	System	24 Sep 2020 16:51:08
User entered 'No (N)'	System	24 Sep 2020 16:51:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:51:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '428676a7-5d91-40e4-be29-9f7f3ff2dbbb'	System	24 Sep 2020 16:51:08
User entered '24 Sep 2020 12:51'	System	24 Sep 2020 16:51:08

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 4'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:43:08', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '912014e7-e825-4c85-9b79-ecd758d6a0de' User entered 'Yes (Y)'	System	25 Sep 2020 22:43:22
	System	25 Sep 2020 22:43:22

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:43:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '912014e7-e825-4c85-9b79-ecd758d6a0de' User entered '96.9'	System	25 Sep 2020 22:43:22
	System	25 Sep 2020 22:43:22

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:43:16', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '912014e7-e825-4c85-9b79-ecd758d6a0de' User entered 'No (N)'	System	25 Sep 2020 22:43:22
	System	25 Sep 2020 22:43:22

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:43:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '912014e7-e825-4c85-9b79-ecd758d6a0de' User entered '25 Sep 2020 18:43'	System	25 Sep 2020 22:43:22
	System	25 Sep 2020 22:43:22

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 5'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:04:31', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0cdeae04-1721-4525-a1ad-0355b7baba29' User entered 'Yes (Y)'	System	26 Sep 2020 16:04:57
	System	26 Sep 2020 16:04:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:04:37', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0cdeae04-1721-4525-a1ad-0355b7baba29' User entered '96.9'	System	26 Sep 2020 16:04:57
	System	26 Sep 2020 16:04:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:04:44', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0cdeae04-1721-4525-a1ad-0355b7baba29' User entered 'No (N)'	System	26 Sep 2020 16:04:57
	System	26 Sep 2020 16:04:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:04:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0cdeae04-1721-4525-a1ad-0355b7baba29' User entered '26 Sep 2020 12:04'	System	26 Sep 2020 16:04:57
	System	26 Sep 2020 16:04:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 6'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:27', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e7b9128c-2f07-43fa-bfce-2fcb8065caa1' User entered 'Yes (Y)'	System	28 Sep 2020 04:17:37
	System	28 Sep 2020 04:17:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:31', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e7b9128c-2f07-43fa-bfce-2fcb8065caa1' User entered '96.8'	System	28 Sep 2020 04:17:37
	System	28 Sep 2020 04:17:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:33', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e7b9128c-2f07-43fa-bfce-2fcb8065caa1'	System	28 Sep 2020 04:17:37
User entered 'No (N)'	System	28 Sep 2020 04:17:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:36', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e7b9128c-2f07-43fa-bfce-2fcb8065caa1' User entered '28 Sep 2020 00:17'	System	28 Sep 2020 04:17:37
	System	28 Sep 2020 04:17:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 7'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:45', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bff99a34-353a-4f56-a1f2-b196349427d3'	System	29 Sep 2020 03:31:57
User entered 'Yes (Y)'	System	29 Sep 2020 03:31:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bff99a34-353a-4f56-a1f2-b196349427d3'	System	29 Sep 2020 03:31:57
User entered '96.8'	System	29 Sep 2020 03:31:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bff99a34-353a-4f56-a1f2-b196349427d3'	System	29 Sep 2020 03:31:57
User entered 'No (N)'	System	29 Sep 2020 03:31:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:54', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bff99a34-353a-4f56-a1f2-b196349427d3' User entered '28 Sep 2020 23:31'	System	29 Sep 2020 03:31:57
	System	29 Sep 2020 03:31:57

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:26', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e6d01cd9-6811-4168-849a-da11c661f8b1' User entered 'None (1)'	System	22 Sep 2020 21:14:44
	System	22 Sep 2020 21:14:44

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:31', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e6d01cd9-6811-4168-849a-da11c661f8b1' User entered 'No (N)'	System	22 Sep 2020 21:14:44
	System	22 Sep 2020 21:14:44

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:35', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e6d01cd9-6811-4168-849a-da11c661f8b1' User entered 'No (N)'	System	22 Sep 2020 21:14:44
	System	22 Sep 2020 21:14:44

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:38', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e6d01cd9-6811-4168-849a-da11c661f8b1' User entered 'None (1)'	System	22 Sep 2020 21:14:44
	System	22 Sep 2020 21:14:44

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:41', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e6d01cd9-6811-4168-849a-da11c661f8b1' User entered '22 Sep 2020 17:14'	System	22 Sep 2020 21:14:44
	System	22 Sep 2020 21:14:44

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '35803304-9b26-4d8e-bde9-bb042c11f050'	System	23 Sep 2020 00:59:35
User entered 'None (1)'	System	23 Sep 2020 00:59:35

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '35803304-9b26-4d8e-bde9-bb042c11f050'	System	23 Sep 2020 00:59:35
User entered 'No (N)'	System	23 Sep 2020 00:59:35

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '35803304-9b26-4d8e-bde9-bb042c11f050' User entered 'No (N)'	System	23 Sep 2020 00:59:35
	System	23 Sep 2020 00:59:35

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:28', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '35803304-9b26-4d8e-bde9-bb042c11f050'	System	23 Sep 2020 00:59:35
User entered 'None (1)'	System	23 Sep 2020 00:59:35

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:31', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '35803304-9b26-4d8e-bde9-bb042c11f050' User entered '22 Sep 2020 20:59'	System	23 Sep 2020 00:59:35
	System	23 Sep 2020 00:59:35

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 2'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a30b5ec1-a3ef-446d-9bb0-c30db37d05ba'	System	23 Sep 2020 16:04:30
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 16:04:30

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a30b5ec1-a3ef-446d-9bb0-c30db37d05ba' User entered 'No (N)'	System	23 Sep 2020 16:04:30
	System	23 Sep 2020 16:04:30

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a30b5ec1-a3ef-446d-9bb0-c30db37d05ba' User entered 'No (N)'	System	23 Sep 2020 16:04:30
	System	23 Sep 2020 16:04:30

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a30b5ec1-a3ef-446d-9bb0-c30db37d05ba' User entered 'None (1)'	System	23 Sep 2020 16:04:30
	System	23 Sep 2020 16:04:30

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:03:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a30b5ec1-a3ef-446d-9bb0-c30db37d05ba' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 16:04:30
	System	23 Sep 2020 16:04:30

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 3'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '50637234-abfe-49dc-b24f-4cca9b2b2d62'	System	24 Sep 2020 16:50:43
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 16:50:43

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:23', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '50637234-abfe-49dc-b24f-4cca9b2b2d62' User entered 'No (N)'	System	24 Sep 2020 16:50:43
	System	24 Sep 2020 16:50:43

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:37', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '50637234-abfe-49dc-b24f-4cca9b2b2d62' User entered 'No (N)'	System	24 Sep 2020 16:50:43
	System	24 Sep 2020 16:50:43

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:36', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '50637234-abfe-49dc-b24f-4cca9b2b2d62'	System	24 Sep 2020 16:50:43
User entered 'None (1)'	System	24 Sep 2020 16:50:43

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:41', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '50637234-abfe-49dc-b24f-4cca9b2b2d62' User entered '24 Sep 2020 12:50'	System	24 Sep 2020 16:50:43
	System	24 Sep 2020 16:50:43

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 4'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:34', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6a665955-3395-4e7f-a7a3-5fcfde25a9b2'	System	25 Sep 2020 22:43:08
User entered 'None (1)'	System	25 Sep 2020 22:43:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:54', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6a665955-3395-4e7f-a7a3-5fcfde25a9b2'	System	25 Sep 2020 22:43:08
User entered 'No (N)'	System	25 Sep 2020 22:43:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6a665955-3395-4e7f-a7a3-5fcfde25a9b2'	System	25 Sep 2020 22:43:08
User entered 'No (N)'	System	25 Sep 2020 22:43:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6a665955-3395-4e7f-a7a3-5fcfde25a9b2'	System	25 Sep 2020 22:43:08
User entered 'None (1)'	System	25 Sep 2020 22:43:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:43:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '6a665955-3395-4e7f-a7a3-5fcfde25a9b2' User entered '25 Sep 2020 18:43'	System	25 Sep 2020 22:43:08
	System	25 Sep 2020 22:43:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 5'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1846c022-a285-4809-b6c4-4f9d986d5785'	System	26 Sep 2020 16:03:15
User entered 'None (1)'	System	26 Sep 2020 16:03:15

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1846c022-a285-4809-b6c4-4f9d986d5785'	System	26 Sep 2020 16:03:15
User entered 'No (N)'	System	26 Sep 2020 16:03:15

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:09', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1846c022-a285-4809-b6c4-4f9d986d5785' User entered 'No (N)'	System	26 Sep 2020 16:03:15
	System	26 Sep 2020 16:03:15

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1846c022-a285-4809-b6c4-4f9d986d5785'	System	26 Sep 2020 16:03:15
User entered 'None (1)'	System	26 Sep 2020 16:03:15

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1846c022-a285-4809-b6c4-4f9d986d5785'	System	26 Sep 2020 16:03:15
User entered '26 Sep 2020 12:02'	System	26 Sep 2020 16:03:15

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 6'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8c8be1f-0923-4297-bc69-defbf7ab2ae7' User entered 'None (1)'	System	28 Sep 2020 04:17:26
	System	28 Sep 2020 04:17:26

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:15', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8c8be1f-0923-4297-bc69-defbf7ab2ae7' User entered 'No (N)'	System	28 Sep 2020 04:17:26
	System	28 Sep 2020 04:17:26

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8c8be1f-0923-4297-bc69-defbf7ab2ae7' User entered 'No (N)'	System	28 Sep 2020 04:17:26
	System	28 Sep 2020 04:17:26

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8c8be1f-0923-4297-bc69-defbf7ab2ae7' User entered 'None (1)'	System	28 Sep 2020 04:17:26
	System	28 Sep 2020 04:17:26

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:21', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8c8be1f-0923-4297-bc69-defbf7ab2ae7' User entered '28 Sep 2020 00:17'	System	28 Sep 2020 04:17:26
	System	28 Sep 2020 04:17:26

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 7'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8d7ea88-7d36-4820-a2af-6010439779c9'	System	29 Sep 2020 03:32:08
User entered 'None (1)'	System	29 Sep 2020 03:32:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:31:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8d7ea88-7d36-4820-a2af-6010439779c9' User entered 'No (N)'	System	29 Sep 2020 03:32:08
	System	29 Sep 2020 03:32:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8d7ea88-7d36-4820-a2af-6010439779c9' User entered 'No (N)'	System	29 Sep 2020 03:32:08
	System	29 Sep 2020 03:32:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8d7ea88-7d36-4820-a2af-6010439779c9' User entered 'None (1)'	System	29 Sep 2020 03:32:08
	System	29 Sep 2020 03:32:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd8d7ea88-7d36-4820-a2af-6010439779c9' User entered '28 Sep 2020 23:32'	System	29 Sep 2020 03:32:08
	System	29 Sep 2020 03:32:08

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:45', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:52', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:54', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'None (0)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:14:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered 'No (N)'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T17:15:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3ee0d277-c3fe-4cba-988a-7d2b936af1d2'	System	22 Sep 2020 21:15:04
User entered '22 Sep 2020 17:15'	System	22 Sep 2020 21:15:04

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:43', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:45', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:49', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:58:53', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'None (0)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered 'No (N)'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-22T20:59:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '42474ace-8308-4bc1-829b-a0c3bdbf54a9' User entered '22 Sep 2020 20:59'	System	23 Sep 2020 00:59:15
	System	23 Sep 2020 00:59:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 2'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:21', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:38', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:42', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:44', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'None (0)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered 'No (N)'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-23T12:02:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '72635ff0-1f03-4a63-87f5-1a96f6ff5301' User entered '23 Sep 2020 12:02'	System	23 Sep 2020 16:04:15
	System	23 Sep 2020 16:04:15

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 3'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:49:51', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:49:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:08', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98' User entered 'None (0)'	System	24 Sep 2020 16:50:19
	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98'	System	24 Sep 2020 16:50:19
User entered 'No (N)'	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-24T12:50:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '24a42e2d-77e7-4ec6-adbe-4097197b4e98'	System	24 Sep 2020 16:50:19
User entered '24 Sep 2020 12:50'	System	24 Sep 2020 16:50:19

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 4'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba'	System	25 Sep 2020 22:42:34
User entered 'No interference with activity (1)'	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:12', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'None (0)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:15', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'None (0)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'None (0)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'None (0)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:22', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'None (0)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:25', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered 'No (N)'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-25T18:42:30', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'a4d0f34f-53cd-4039-9900-de419085edba' User entered '25 Sep 2020 18:42'	System	25 Sep 2020 22:42:34
	System	25 Sep 2020 22:42:34

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 5'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:38', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:41', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:43', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:44', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'None (0)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:01:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered 'No (N)'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-26T12:02:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2cf55844-100f-42af-9073-1ca61eb31b4d' User entered '26 Sep 2020 12:02'	System	26 Sep 2020 16:03:01
	System	26 Sep 2020 16:03:01

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 6'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:16:56', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:16:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:16:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:05', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'None (0)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered 'No (N)'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T00:17:09', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '2365f5dd-1412-48e2-94c9-08b6eb1637c7' User entered '28 Sep 2020 00:17'	System	28 Sep 2020 04:17:12
	System	28 Sep 2020 04:17:12

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	22 Sep 2020 20:51:37
User entered 'Day 7'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:08', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:13', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:15', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'None (0)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:17', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered 'No (N)'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-09-28T23:32:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '25d81c0c-9a43-4e18-8700-688feeb7bf9c' User entered '28 Sep 2020 23:32'	System	29 Sep 2020 03:32:24
	System	29 Sep 2020 03:32:24

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:51:37

US3742034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:51:37

US3742034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:07

US3742034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '29 Sep 2020'	Hassan Haji (b) (4)	06 Oct 2020 18:59:07

US3742034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:07

US3742034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Hassan Haji (b) (4)	06 Oct 2020 18:59:07

US3742034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:10

US3742034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '1'	System	06 Oct 2020 18:59:10

US3742034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:51

US3742034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '6 Oct 2020'	Hassan Haji (b) (4)	06 Oct 2020 18:59:51

US3742034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:51

US3742034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Hassan Haji (b) (4)	06 Oct 2020 18:59:51

US3742034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 18:59:57

US3742034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	06 Oct 2020 18:59:57

US3742034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 19:05:27

US3742034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '13 Oct 2020'	Hassan Haji (b) (4)	13 Oct 2020 19:05:27

US3742034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	13 Oct 2020 19:05:27

US3742034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 19:05:27

US3742034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 19:07:13

US3742034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	13 Oct 2020 19:07:13

US3742034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:09

US3742034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '20 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:09

US3742034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Clinic (Clinic)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:09

US3742034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered 'VISIT3'	System	20 Oct 2020 20:01:09

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered empty.	System	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered empty.	System	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered empty.	System	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered empty.	System	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered empty.	System	20 Oct 2020 20:01:38

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20

US3742034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20

US3742034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:31

US3742034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '20 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:31

US3742034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:55

US3742034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '20 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 20:01:55

US3742034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered '15:17'	Kaitlin Mason (b) (4)	20 Oct 2020 20:01:55

US3742034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:20
User entered '20 Oct 2020 15:17'	System	20 Oct 2020 20:01:55

US3742034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:00:29
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:02:05

US3742034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered '1'	System	20 Oct 2020 20:02:05

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 64'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-10-27T12:00:55', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0af276f2-329e-4a40-add4-09ccaf2fa631' User entered 'No (N)'	System	27 Oct 2020 16:01:29
	System	27 Oct 2020 16:01:29

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-10-27T12:01:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0af276f2-329e-4a40-add4-09ccaf2fa631'	System	27 Oct 2020 16:01:29
User entered 'No (N)'	System	27 Oct 2020 16:01:29

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-10-27T12:01:09', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '0af276f2-329e-4a40-add4-09ccaf2fa631' User entered '27 Oct 2020 12:01:09'	System	27 Oct 2020 16:01:29
	System	27 Oct 2020 16:01:29

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '25 Oct 2020 00:01'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '29 Oct 2020 23:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 71'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-01T00:01:48', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd831d96a-9de4-44f0-9007-c5f3ad57d1da' User entered 'No (N)'	System	01 Nov 2020 04:02:11
	System	01 Nov 2020 04:02:11

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-01T00:01:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd831d96a-9de4-44f0-9007-c5f3ad57d1da'	System	01 Nov 2020 04:02:11
User entered 'No (N)'	System	01 Nov 2020 04:02:11

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-01T00:02:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'd831d96a-9de4-44f0-9007-c5f3ad57d1da' User entered '01 Nov 2020 00:02:02'	System	01 Nov 2020 04:02:11
	System	01 Nov 2020 04:02:11

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '01 Nov 2020 00:01'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '05 Nov 2020 23:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered 'Day 78'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-08T08:53:25', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b7bce6a0-c201-4044-9cf7-6909fa530b2c' User entered 'No (N)'	System	08 Nov 2020 13:53:39
	System	08 Nov 2020 13:53:39

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-08T08:53:32', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b7bce6a0-c201-4044-9cf7-6909fa530b2c'	System	08 Nov 2020 13:53:39
User entered 'No (N)'	System	08 Nov 2020 13:53:39

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E2CE4B45-8119-45AD-B637-3DCBAF666CF1)', Time: '2020-11-08T08:53:35', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'b7bce6a0-c201-4044-9cf7-6909fa530b2c' User entered '08 Nov 2020 08:53:35'	System	08 Nov 2020 13:53:39
	System	08 Nov 2020 13:53:39

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '08 Nov 2020 00:01'	System	26 Aug 2020 00:06:52

US3742034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:28:15
Data entry locked.	System	26 Aug 2020 00:06:52
User entered '12 Nov 2020 23:59'	System	26 Aug 2020 00:06:52

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (B9E29941-55E8-4E9C-ADB2-E4CFEBF4E3EA)', Time: '2020-12-07T13:54:20', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '027ea6c7-8ce6-4e57-8509-0e9b0f8b900c' User entered 'No (N)'	System	07 Dec 2020 18:54:31

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (B9E29941-55E8-4E9C-ADB2-E4CFEBF4E3EA)', Time: '2020-12-07T13:54:26', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '027ea6c7-8ce6-4e57-8509-0e9b0f8b900c' User entered 'No (N)'	System	07 Dec 2020 18:54:31

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9E29941-55E8-4E9C-ADB2-E4CFEBF4E3EA)', Time: '2020-12-07T13:54:28', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '027ea6c7-8ce6-4e57-8509-0e9b0f8b900c' User entered '07 Dec 2020 13:54:28'	System	07 Dec 2020 18:54:31
	System	07 Dec 2020 18:54:31

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-10T10:12:21', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c22c6c6d-da5d-42f5-b185-cce2706d5aaf'	System	10 Dec 2020 15:12:32
User entered 'No (N)'	System	10 Dec 2020 15:12:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-10T10:12:26', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c22c6c6d-da5d-42f5-b185-cce2706d5aaf'	System	10 Dec 2020 15:12:32
User entered 'No (N)'	System	10 Dec 2020 15:12:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-10T10:12:28', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'c22c6c6d-da5d-42f5-b185-cce2706d5aaf' User entered '10 Dec 2020 10:12:28'	System	10 Dec 2020 15:12:32
	System	10 Dec 2020 15:12:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-17T02:02:32', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'be24dda3-5b27-4eb6-931c-f82362719f65'	System	17 Dec 2020 07:02:46
User entered 'No (N)'	System	17 Dec 2020 07:02:46

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-17T02:02:37', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'be24dda3-5b27-4eb6-931c-f82362719f65'	System	17 Dec 2020 07:02:46
User entered 'No (N)'	System	17 Dec 2020 07:02:46

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-17T02:02:40', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'be24dda3-5b27-4eb6-931c-f82362719f65' User entered '17 Dec 2020 02:02:40'	System	17 Dec 2020 07:02:46
	System	17 Dec 2020 07:02:46

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-24T00:40:50', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '7fbf4bfa-c88f-4e13-ab7d-a8635a7f1b77'	System	24 Dec 2020 05:41:09
User entered 'No (N)'	System	24 Dec 2020 05:41:09

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-24T00:40:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '7fbf4bfa-c88f-4e13-ab7d-a8635a7f1b77'	System	24 Dec 2020 05:41:09
User entered 'No (N)'	System	24 Dec 2020 05:41:09

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-24T00:41:01', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '7fbf4bfa-c88f-4e13-ab7d-a8635a7f1b77'	System	24 Dec 2020 05:41:09
User entered '24 Dec 2020 00:41:01'	System	24 Dec 2020 05:41:09

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-31T00:52:59', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'fb74a9e5-5fb6-4366-9354-533061726c90' User entered 'No (N)'	System	31 Dec 2020 05:53:14
	System	31 Dec 2020 05:53:14

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-31T00:53:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'fb74a9e5-5fb6-4366-9354-533061726c90'	System	31 Dec 2020 05:53:14
User entered 'No (N)'	System	31 Dec 2020 05:53:14

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2020-12-31T00:53:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'fb74a9e5-5fb6-4366-9354-533061726c90' User entered '31 Dec 2020 00:53:10'	System	31 Dec 2020 05:53:14
	System	31 Dec 2020 05:53:14

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-07T00:36:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '054c788e-36c5-4646-8331-96ee67db9ab6' User entered 'No (N)'	System	07 Jan 2021 05:36:18
	System	07 Jan 2021 05:36:18

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-07T00:36:10', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '054c788e-36c5-4646-8331-96ee67db9ab6'	System	07 Jan 2021 05:36:18
User entered 'No (N)'	System	07 Jan 2021 05:36:18

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-07T00:36:14', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '054c788e-36c5-4646-8331-96ee67db9ab6' User entered '07 Jan 2021 00:36:14'	System	07 Jan 2021 05:36:18
	System	07 Jan 2021 05:36:18

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-14T08:49:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '08c29742-2b16-4b19-a641-d69312202556'	System	14 Jan 2021 13:50:32
User entered 'No (N)'	System	14 Jan 2021 13:50:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-14T08:49:43', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '08c29742-2b16-4b19-a641-d69312202556'	System	14 Jan 2021 13:50:32
User entered 'Yes (Y)'	System	14 Jan 2021 13:50:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-14T08:50:01', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '08c29742-2b16-4b19-a641-d69312202556'	System	14 Jan 2021 13:50:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 13:50:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-14T08:50:22', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '08c29742-2b16-4b19-a641-d69312202556' User entered '14 Jan 2021 08:50:22'	System	14 Jan 2021 13:50:32
	System	14 Jan 2021 13:50:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-21T05:30:47', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '94d0af81-9fbb-45e3-b404-31885eef0b64' User entered 'No (N)'	System	21 Jan 2021 10:31:21
	System	21 Jan 2021 10:31:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-21T05:30:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '94d0af81-9fbb-45e3-b404-31885eef0b64' User entered 'Yes (Y)'	System	21 Jan 2021 10:31:21
	System	21 Jan 2021 10:31:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-21T05:31:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '94d0af81-9fbb-45e3-b404-31885eef0b64'	System	21 Jan 2021 10:31:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Jan 2021 10:31:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-21T05:31:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '94d0af81-9fbb-45e3-b404-31885eef0b64' User entered '21 Jan 2021 05:31:11'	System	21 Jan 2021 10:31:21
	System	21 Jan 2021 10:31:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-28T11:49:58', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bb35bbe4-1bf7-4a87-a53e-75f9abf59dea' User entered 'No (N)'	System	28 Jan 2021 16:50:21
	System	28 Jan 2021 16:50:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-28T11:50:04', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bb35bbe4-1bf7-4a87-a53e-75f9abf59dea'	System	28 Jan 2021 16:50:21
User entered 'No (N)'	System	28 Jan 2021 16:50:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-01-28T11:50:18', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'bb35bbe4-1bf7-4a87-a53e-75f9abf59dea' User entered '28 Jan 2021 11:50:18'	System	28 Jan 2021 16:50:21
	System	28 Jan 2021 16:50:21

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-04T04:47:02', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '018c833e-ed24-480b-9b0f-024c714f2227'	System	04 Feb 2021 09:47:15
User entered 'No (N)'	System	04 Feb 2021 09:47:15

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-04T04:47:07', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '018c833e-ed24-480b-9b0f-024c714f2227'	System	04 Feb 2021 09:47:15
User entered 'No (N)'	System	04 Feb 2021 09:47:15

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-04T04:47:09', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '018c833e-ed24-480b-9b0f-024c714f2227' User entered '04 Feb 2021 04:47:09'	System	04 Feb 2021 09:47:15
	System	04 Feb 2021 09:47:15

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:08:48', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered 'Yes (Y)'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:08:46', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered 'No (N)'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:08:57', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered 'Yes (Y)'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf'	System	13 Feb 2021 11:24:43
User entered '1'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf'	System	13 Feb 2021 11:24:43
User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf'	System	13 Feb 2021 11:24:43
User entered '1'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '1'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:19', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '0'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:28', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf'	System	13 Feb 2021 11:24:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:38', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered 'Yes (Y)'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:09:44', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf'	System	13 Feb 2021 11:24:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-11T03:10:03', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '91348f92-e20e-4a6e-8802-09e40c9343cf' User entered '11 Feb 2021 03:10:03'	System	13 Feb 2021 11:24:43
	System	13 Feb 2021 11:24:43

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-18T07:28:06', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ed9b7483-1aa2-48df-be16-c970b882df89' User entered 'No (N)'	System	18 Feb 2021 12:28:30
	System	18 Feb 2021 12:28:30

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-18T07:28:11', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ed9b7483-1aa2-48df-be16-c970b882df89' User entered 'No (N)'	System	18 Feb 2021 12:28:30
	System	18 Feb 2021 12:28:30

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-18T07:28:28', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ed9b7483-1aa2-48df-be16-c970b882df89' User entered '18 Feb 2021 07:28:28'	System	18 Feb 2021 12:28:30
	System	18 Feb 2021 12:28:30

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-25T00:42:26-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ee3b16d8-a240-429f-bc17-539843b3c097'	System	25 Feb 2021 14:28:03
User entered 'No (N)'	System	25 Feb 2021 14:28:03

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-25T00:42:32-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ee3b16d8-a240-429f-bc17-539843b3c097'	System	25 Feb 2021 14:28:03
User entered 'No (N)'	System	25 Feb 2021 14:28:03

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-25T00:42:35-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'ee3b16d8-a240-429f-bc17-539843b3c097'	System	25 Feb 2021 14:28:03
User entered '25 Feb 2021 05:42:35'	System	25 Feb 2021 14:28:03

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-04T09:54:06-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f782a276-2bd1-4bb8-a789-5e87dd347c24'	System	04 Mar 2021 14:54:26
User entered 'No (N)'	System	04 Mar 2021 14:54:26

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-04T09:54:15-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f782a276-2bd1-4bb8-a789-5e87dd347c24'	System	04 Mar 2021 14:54:26
User entered 'No (N)'	System	04 Mar 2021 14:54:26

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-04T09:54:17-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'f782a276-2bd1-4bb8-a789-5e87dd347c24'	System	04 Mar 2021 14:54:26
User entered '04 Mar 2021 09:54:17'	System	04 Mar 2021 14:54:26

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-11T05:46:27-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1efaead8-4e93-401a-8761-590f560317e3'	System	11 Mar 2021 10:46:39
User entered 'No (N)'	System	11 Mar 2021 10:46:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-11T05:46:31-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1efaead8-4e93-401a-8761-590f560317e3'	System	11 Mar 2021 10:46:39
User entered 'No (N)'	System	11 Mar 2021 10:46:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-11T05:46:35-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1efaead8-4e93-401a-8761-590f560317e3' User entered '11 Mar 2021 05:46:35'	System	11 Mar 2021 10:46:39
	System	11 Mar 2021 10:46:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-18T04:53:02-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3d36db62-c5d3-4b8a-b851-f0ba86c3a649'	System	18 Mar 2021 08:53:11
User entered 'No (N)'	System	18 Mar 2021 08:53:11

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-18T04:53:04-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3d36db62-c5d3-4b8a-b851-f0ba86c3a649' User entered 'No (N)'	System	18 Mar 2021 08:53:11
	System	18 Mar 2021 08:53:11

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-18T04:53:08-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3d36db62-c5d3-4b8a-b851-f0ba86c3a649' User entered '18 Mar 2021 04:53:08'	System	18 Mar 2021 08:53:11
	System	18 Mar 2021 08:53:11

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-25T08:35:52-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1c55d841-9ee9-49a5-b90b-7638e5694154'	System	25 Mar 2021 12:36:06
User entered 'No (N)'	System	25 Mar 2021 12:36:06

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-25T08:35:57-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1c55d841-9ee9-49a5-b90b-7638e5694154'	System	25 Mar 2021 12:36:06
User entered 'No (N)'	System	25 Mar 2021 12:36:06

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-03-25T08:36:02-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '1c55d841-9ee9-49a5-b90b-7638e5694154'	System	25 Mar 2021 12:36:06
User entered '25 Mar 2021 08:36:02'	System	25 Mar 2021 12:36:06

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-01T09:55:26-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e327060e-500f-47aa-9a63-b38a4dc7dd4b' User entered 'No (N)'	System	01 Apr 2021 13:55:39
	System	01 Apr 2021 13:55:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-01T09:55:31-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e327060e-500f-47aa-9a63-b38a4dc7dd4b' User entered 'No (N)'	System	01 Apr 2021 13:55:39
	System	01 Apr 2021 13:55:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-01T09:55:36-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'e327060e-500f-47aa-9a63-b38a4dc7dd4b'	System	01 Apr 2021 13:55:39
User entered '01 Apr 2021 09:55:36'	System	01 Apr 2021 13:55:39

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-08T05:30:22-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'eb250f6d-97c5-40b1-b297-c16289814ed3' User entered 'No (N)'	System	08 Apr 2021 09:30:35
	System	08 Apr 2021 09:30:35

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-08T05:30:27-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'eb250f6d-97c5-40b1-b297-c16289814ed3'	System	08 Apr 2021 09:30:35
User entered 'No (N)'	System	08 Apr 2021 09:30:35

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-08T05:30:29-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: 'eb250f6d-97c5-40b1-b297-c16289814ed3'	System	08 Apr 2021 09:30:35
User entered '08 Apr 2021 05:30:29'	System	08 Apr 2021 09:30:35

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-15T05:00:44-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '967008e2-97c4-4d46-a3b2-8a2e0487e8bf' User entered 'No (N)'	System	19 Apr 2021 13:21:38
	System	19 Apr 2021 13:21:38

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-15T05:00:49-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '967008e2-97c4-4d46-a3b2-8a2e0487e8bf' User entered 'No (N)'	System	19 Apr 2021 13:21:38
	System	19 Apr 2021 13:21:38

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-15T05:00:53-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '967008e2-97c4-4d46-a3b2-8a2e0487e8bf'	System	19 Apr 2021 13:21:38
User entered '15 Apr 2021 05:00:53'	System	19 Apr 2021 13:21:38

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-22T05:37:25-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3e8c5ef4-c69d-4362-bb9d-717e4fc0bdff' User entered 'No (N)'	System	22 Apr 2021 09:37:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-22T05:37:28-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3e8c5ef4-c69d-4362-bb9d-717e4fc0bdff' User entered 'No (N)'	System	22 Apr 2021 09:37:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-22T05:37:30-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '3e8c5ef4-c69d-4362-bb9d-717e4fc0bdff'	System	22 Apr 2021 09:37:32
User entered '22 Apr 2021 05:37:30'	System	22 Apr 2021 09:37:32

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-29T05:09:32-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8baf66b8-b200-4ea5-84f3-95649c607955'	System	29 Apr 2021 09:09:58
User entered 'No (N)'	System	29 Apr 2021 09:09:58

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

Have you been exposed to someone with 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 (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-29T05:09:36-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8baf66b8-b200-4ea5-84f3-95649c607955'	System	29 Apr 2021 09:09:58
User entered 'No (N)'	System	29 Apr 2021 09:09:58

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-04-29T05:09:40-04:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '8baf66b8-b200-4ea5-84f3-95649c607955'	System	29 Apr 2021 09:09:58
User entered '29 Apr 2021 05:09:40'	System	29 Apr 2021 09:09:58

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 00:34:13

US3742034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:34:13
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 00:34:13

US3742034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:29:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:34:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-28T14:52:21-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '9609048c-e65f-4298-8522-faeb4192b6a8'	System	28 Feb 2021 19:52:30
User entered 'No (N)'	System	28 Feb 2021 19:52:30

US3742034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:29:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:34:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8291EFCA-4357-437A-B3E4-9121F8F4BAAB)', Time: '2021-02-28T14:52:28-05:00', User OID: 'PatientReportedOutcome (US3742034)', ODM File OID: '9609048c-e65f-4298-8522-faeb4192b6a8' User entered '28 Feb 2021 19:52:28'	System	28 Feb 2021 19:52:30
	System	28 Feb 2021 19:52:30

US3742034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:35:06
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 16:56:49

US3742034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:35:06
User entered '17 Nov 2020'	Sherry McCammon (b) (4)	04 Dec 2020 16:56:49

US3742034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:35:06
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	04 Dec 2020 16:56:49

US3742034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:35:06
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 16:56:49

US3742034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:35:06
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 16:56:54

US3742034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:44:10
User entered 'I'	System	04 Dec 2020 16:56:54

US3742034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 16:06:09

US3742034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 16:06:09

US3742034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Dec 2020 16:06:09

US3742034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 16:06:09

US3742034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 16:06:13

US3742034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User entered 'I'	System	21 Dec 2020 16:06:13

US3742034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	21 Jan 2021 16:11:59
	(b) (4)	

US3742034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '21 Jan 2021'	Hassan Haji (b) (4)	21 Jan 2021 16:11:59
	(b) (4)	

US3742034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	21 Jan 2021 16:11:59
	(b) (4)	

US3742034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	21 Jan 2021 16:11:59
	(b) (4)	

US3742034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	21 Jan 2021 16:12:03
	(b) (4)	

US3742034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User entered 'I'	System	21 Jan 2021 16:12:03

US3742034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 19:11:31
	(b) (4)	

US3742034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '19 Feb 2021'	Sherry McCammon (b) (4)	22 Feb 2021 19:11:31
	(b) (4)	

US3742034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Feb 2021 19:11:31
	(b) (4)	

US3742034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 19:11:31
	(b) (4)	

US3742034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 19:11:48
	(b) (4)	

US3742034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:21:09
User entered 'I'	System	22 Feb 2021 19:11:48

US3742034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:35:51

US3742034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 13:35:51

US3742034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 13:35:51

US3742034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered 'VISIT4'	System	24 Mar 2021 13:35:51

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered empty.	System	30 Mar 2021 19:02:30

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered empty.	System	30 Mar 2021 19:02:30

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered empty.	System	30 Mar 2021 19:02:30

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered empty.	System	30 Mar 2021 19:02:30

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:02:30
	(b) (4)	

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered empty.	System	30 Mar 2021 19:02:30

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46

US3742034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46

US3742034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:36:01

US3742034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:36:01

US3742034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:36:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:36:25

US3742034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User closed query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:36:24
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:36:26
Query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.'	Sherry McCammon (b) (4)	08 Apr 2021 20:21:27
answered with 'Collection date is correct Accession #1F60FNF' (Site from DM).	(b) (4)	
User opened query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:55:50
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 13:36:25

US3742034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:36:26
	(b) (4)	
User entered '15:05'	(b) (4), (b) (6)	24 Mar 2021 13:36:25

US3742034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered '23 Mar 2021 15:05'	System	24 Mar 2021 13:36:25

US3742034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:36:34

US3742034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:46
User entered '1'	System	24 Mar 2021 13:36:34

US3742034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 13:32:23

US3742034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
	(b) (4)	
User entered '19 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 13:32:23

US3742034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:32:23

US3742034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:32:23

US3742034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 13:32:33

US3742034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 13:32:33

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:09:19

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:09:19

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) System	08 Jan 2021 16:09:25
	(b) (4), (b) (6)	08 Jan 2021 16:09:25
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered empty.	System	08 Jan 2021 16:09:19
	(b) (4), (b) (6)	08 Jan 2021 16:09:19

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 16:09:19

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.'" (Site from DM). User signature succeeded.	(b) (4), (b) (6) Milagritos Tapia (b) (4)	19 Apr 2021 13:02:38 08 Apr 2021 19:21:04
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.'" answered with 'updated' (Site from DM). Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	08 Apr 2021 19:07:52
User entered '07 Jan 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	08 Apr 2021 19:07:36
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.'" (Site from DM). User signature succeeded.	(b) (4), (b) (6) Karen Kotloff (b) (4)	07 Apr 2021 16:21:57 23 Feb 2021 16:31:50
User entered '24 Dec 2020'	(b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 19:21:04
User entered '0'	Kaitlin Mason (b) (4)	08 Apr 2021 19:07:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:15:42

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 19:21:04
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kaitlin Mason (b) (4)	08 Apr 2021 19:07:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:15:42

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 12:32:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 12:32:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered empty.	System	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered empty.	System	08 Jan 2021 16:17:55

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:25:39

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:25:39

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '15:21'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:25:39

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '7 Jan 2021 15:21'	System	08 Jan 2021 16:25:39

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:26:17

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:26:17

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '15:24'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:26:17

US3742034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:26:00
User entered '7 Jan 2021 15:24'	System	08 Jan 2021 16:26:17

US3742034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:29:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:17
User closed query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'symptoms did not last more than 48 hours' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:06:04
User opened query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 12:53:14
User signature succeeded.	(b) (4), (b) (6)	23 Mar 2021 06:06:05
DataPoint Verified.	Karen Kotloff (b) (4) (b) (4), (b) (6)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Feb 2021 16:07:13 13 Oct 2020 19:03:14

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:06:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:06:27
Data point term sent to Coder	System	13 Oct 2020 19:05:10
User entered 'headache'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User entered empty.	System	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '8 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User entered empty.	System	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Applicable (NOT APPLICABLE)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:30:59
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with '500 mg Tylenol taken once PO and 400 mg taken once PO on 7OCT2020. Medications updated on Con Med sheet' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:48:05
User entered '0' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 15:47:54
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:19:58
User entered '1'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 15:47:54
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User entered '0'	System	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43
User entered '0'	System	13 Oct 2020 19:04:30

US3742034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:28:43

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:06:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered	System	17 Feb 2021 16:23:12
'USA-US127-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 16:23:12

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:08:38
Query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this. ' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	20 Apr 2021 16:20:11
User opened query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:35:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Ruptured appendix - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 20:49:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 20:49:12
Data point term sent to Coder	System	16 Feb 2021 20:47:55
User entered 'Ruptured appendix'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per the paper SAE form event was also medically significant and life threatening. Please confirm the seriousness of the event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:08:34
Query 'PV Query: Per the paper SAE form event was also medically significant and life threatening. Please confirm the seriousness of the event.' answered with 'yes medically significant and life threatening . Required hospitalization' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:26:42
User opened query 'PV Query: Per the paper SAE form event was also medically significant and life threatening. Please confirm the seriousness of the event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:07:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:51:48
Query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	28 Apr 2021 18:35:05
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Kaitlin Mason (b) (4)	28 Apr 2021 18:34:34
	(b) (4)	
User entered '09 Feb 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	28 Apr 2021 18:34:34
	(b) (4)	
User opened query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 11:25:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '11 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 15:26:05
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 18:11:06
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 18:11:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:11:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 15:26:05
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) (4), (b) (6)	04 Mar 2021 17:51:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 18:11:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	03 Mar 2021 18:11:52
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 'updated' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 18:11:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 18:11:06
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 18:11:06
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 18:11:06
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:11:06
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)	26 Feb 2021 14:09:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:02
	(b) (4)	
DataPoint Un-verified.	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
	(b) (4)	
Signature has been broken.	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change:	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Feb 2021 20:48:39
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Feb 2021 20:48:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 15:26:05
User closed query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:35
Query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:29:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 15:28:57
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 15:28:57
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 15:28:57
User opened query 'PV Query: Thank you for confirming event was medically significant and life threatening. Please update seriousness in eCRF to reflect this.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 13:27:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:33:16
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 12:44:58
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:35:57
User closed query 'Per CDM Response noted. Please update missing information once available.	(b) (4), (b) (6)	26 Feb 2021 19:17:42
' (Site from DM).		
Query 'Per CDM Response noted. Please update missing information once available.	(b) (4), (b) (6)	24 Feb 2021 15:08:53
' answered with 'yes patient was hospitalized 11 feb 2021 and as of 19 feb 2021 patient still hospitalized. No record of patient discharge ' (Site from DM).		
User opened query 'Per CDM Response noted. Please update missing information once available.	(b) (4), (b) (6)	23 Feb 2021 23:24:23
' (Site from DM).		
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 23:24:13
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Currently Hospitalized' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 20:49:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		16 Feb 2021 20:48:39
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	16 Feb 2021 20:48:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:48:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:48:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Feb 2021 20:48:07
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:48:07
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Feb 2021 20:48:07
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:48:07

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	System	16 Feb 2021 20:47:37
	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:51:53
Query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.'	Kaitlin Mason (b) (4)	28 Apr 2021 18:23:57
answered with 'updated' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please note, hospital admission date was changed to 09 Feb 2021 instead of the event date as recently queried. Please update hospital admission date to 11 Feb 2021 and event start date to 09 Feb 2021 as indicated in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 11:25:24
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:02
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
	(b) (4)	
User entered '09 Feb 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:27:50
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '11 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Onset of illness in discharge summary was noted as 02/09, however onset date was reported as 02/11. Please consider updating onset date to 02/09 or else clarify this discrepancy. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:08:42
Query 'PV Query: Onset of illness in discharge summary was noted as 02/09, however onset date was reported as 02/11. Please consider updating onset date to 02/09 or else clarify this discrepancy. ' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:22:39
User opened query 'PV Query: Onset of illness in discharge summary was noted as 02/09, however onset date was reported as 02/11. Please consider updating onset date to 02/09 or else clarify this discrepancy. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:36:45
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:22:12
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	08 Apr 2021 15:26:05
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'discharge summary submitted via fax today.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:03:52
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:51:31
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 18:12:00
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:51

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 18:04:51
User entered '23 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:04:51
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:08:31
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:08:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 20:49:50
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

US3742034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming event was medically significant. Please update seriousness in eCRF to reflect this. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:06:39
Query 'PV Query: Thank you for confirming event was medically significant. Please update seriousness in eCRF to reflect this. ' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 12:48:36
User opened query 'PV Query: Thank you for confirming event was medically significant. Please update seriousness in eCRF to reflect this. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:12:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
User closed query 'Per DM CLR: Please note that there is no Con Procedure listed for treatment of this condition and treatment would be expected for a hospitalized subject. Please review and if applicable add the applicable Con Procedure. ' (Site from DM). Query 'Per DM CLR: Please note that there is no Con Procedure listed for treatment of this condition and treatment would be expected for a hospitalized subject. Please review and if applicable add the applicable Con Procedure. ' answered with 'Updated. Please refer to Con Procedure #1' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 14:57:12 12 Apr 2021 14:50:04
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:49:32
User opened query 'Per DM CLR: Please note that there is no Con Procedure listed for treatment of this condition and treatment would be expected for a hospitalized subject. Please review and if applicable add the applicable Con Procedure. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Milagritos Tapia (b) (4)	12 Apr 2021 00:13:59 08 Apr 2021 15:26:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Apr 2021 12:50:32
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Apr 2021 12:50:32
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Apr 2021 12:46:43
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:39:38
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:39:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 16:39:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:07:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention. 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)	01 Mar 2021 16:08:42
Query 'PV Query: Please provide treatment given for the event including medical intervention. 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 'participant had an appendectomy' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:43:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention. 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)	26 Feb 2021 14:08:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:49:32
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:49:32
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 15:26:05
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:46:15
(Site from DM).		
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 12:50:05
' answered with 'updated' (Site from DM).		
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 12:46:43
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 02:55:15
(Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:39:38
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:39:38
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 16:39:38
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:31:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 15:26:05
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 18:11:52
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 18:11:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:11:52
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:08:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'as per verbal report from safety call day 179. participant still hospitalized' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:52:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:09:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of abdominal CT on 2/16 and 02/22' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 11:25:11
User closed query 'PV Query: Please provide results of abdominal CT on 2/16 and 02/22 ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:08:49
User closed query 'IQVIA Medical query: Please clarify whether small bowel obstruction, abscesses, and left renal mass noted in hospital records meet AE/SAE reporting criteria and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:08:46
Query 'IQVIA Medical query: Please clarify whether small bowel obstruction, abscesses, and left renal mass noted in hospital records meet AE/SAE reporting criteria and update report if appropriate. ' answered with 'Per PI they do not meet AE/SAE reporting criteria as they were associated and a complication of the ruptured appendix. ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 18:28:25
Query 'PV Query: Please provide results of abdominal CT on 2/16 and 02/22 ' answered with 'CT findings included in redacted documents' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:24:43
User opened query 'PV Query: Please provide results of abdominal CT on 2/16 and 02/22 ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:36:26
User opened query 'IQVIA Medical query: Please clarify whether small bowel obstruction, abscesses, and left renal mass noted in hospital records meet AE/SAE reporting criteria and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:36:11
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:22:16
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	08 Apr 2021 15:26:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID -19 PCR test performed at the hospital was negative. Test was performed on 16Feb2021.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:06:25
User entered 'PARTICIPANT WAS FOLLOWED UP DURING A SAFETY CALL AND REPORTED SHE HAD AN EMERGENCY SURGERY FOR RUPTURED APPENDIX. SHE VOLUNTEERED SHE IS CURRENTLY DISCHARGED AS OF 23 FEB 2021' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:59
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 18:13:35
User entered 'PARTICIPANT WAS FOLLOWED UP DURING A SAFETY CALL AND REPORTED SHE HAD AN EMERGENCY SURGERY FOR RUPTURED APPENDIX. SHE VOLUNTEERED SHE IS CURRENTLY DISCHARGED AS OF 26 FEB 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:13:35
User closed query 'PV: Please provide the results of the CT abdomen/pelvis with contrast performed on 11 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:09:12
Query 'PV: Please provide the results of the CT abdomen/pelvis with contrast performed on 11 Feb 2021.' answered with 'Right lower quadrant inflammatory changes compatible with acute appendicitis' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:40:57
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:08:02
User opened query 'PV: Please provide the results of the CT abdomen/pelvis with contrast performed on 11 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:07:50
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:31:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:07:31
User entered 'Participant was followed up during a safety call and reported she had an emergency surgery for ruptured appendix. She volunteered she is currently hospitalized.'	(b) (4), (b) (6)	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 20:47:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 20:49:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:29:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:34:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: ZESTORETIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 12:44:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 12:44:34
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 12:43:18 28 Sep 2020 12:42:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: ZESTORETIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:06:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:06:40
Data point term sent to Coder User entered 'ZESTORETIC'	System Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:05:49 10 Sep 2020 15:05:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per CDM CR: Please update the indication to High Blood Pressure so there is an appropriate match in the MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:20:46
Query 'Per CDM CR: Please update the indication to High Blood Pressure so there is an appropriate match in the MH eCRF. ' answered with 'ADDRESSED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 12:42:40
User entered 'HIGH BLOOD PRESSURE' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 12:42:33
User opened query 'Per CDM CR: Please update the indication to High Blood Pressure so there is an appropriate match in the MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:15:39
User entered 'BLOOD PRESSURE'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:05:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '20/12.5'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:12:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:12:14
User entered 'mg (mg)' reason for change: New Information	Sherry McCammon (b) (4)	10 Sep 2020 15:12:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:05:24
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:05:24
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:05:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:05:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:05:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 15:07:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:07:38
Data point term sent to Coder	System	10 Sep 2020 15:06:52
User entered 'MULTIVITAMIN'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:41:37
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:00:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:00:24
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:47:51
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:06:44

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'tablet (TABLET)'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:06:44
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:06:44

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:06:44

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:06:44

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 23:58:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:58:33
Data point term sent to Coder	System	27 Oct 2020 19:34:03
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 19:33:17
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:09:46
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 Sep 2020 15:09:46
Data point term sent to Coder	System	10 Sep 2020 15:08:56
User entered 'FISH OIL'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:23:46
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:00:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:00:45
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:47:57
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'SUPPLEMENT General Health'	(b) (4), (b) (6)	27 Oct 2020 19:33:17
reason for change: Data Entry Error		
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1200' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:34:53
User entered '1'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'mg (mg)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:53
User entered 'tablet (TABLET)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:33:17
User entered 'UN UNK 2019'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:08:19
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:08:19

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Sep 2020 12:44:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:44:34
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4)	28 Sep 2020 12:43:18 28 Sep 2020 12:43:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:10:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:10:39
Data point term sent to Coder User entered 'VITAMIN D3'	System Sherry McCammon (b) (4)	10 Sep 2020 15:09:59 10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:23:15
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:01:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:01:13
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:48:05
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:20:54
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'NO INDICATION - FOR GENERAL HEALTH AND WELLNESS' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 12:43:22
User entered 'SUPPLEMENT/GENERAL WELLNESS' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 12:43:08
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:16:25
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:23:14
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:34:32
User entered '2000' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:34:08
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:51:29
User entered '1'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'IU (IU)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:08
User entered 'tablet (TABLET)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:09:07
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:09:07

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 13:14:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:14:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:10:39
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 Sep 2020 15:10:39
Data point term sent to Coder User entered 'IRON'	System Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:10:02 10 Sep 2020 15:10:01

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:20:11
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:02:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 15:02:22
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:48:12
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Sep 2020 15:10:01

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '65'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Sep 2020 15:10:01
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:10:01

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:10:01

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:10:01

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 18:59:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:59:17
Data point term sent to Coder	System	13 Oct 2020 18:57:58
User entered 'Tylenol'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'headache'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '500'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'mg (mg)'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	13 Oct 2020 18:58:47
User entered 'as needed (PRN)' reason for change: Data Entry Error	System	13 Oct 2020 18:58:47
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	13 Oct 2020 18:57:57
User entered 'once (ONCE)'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57
	(b) (4)	

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Oct 2020'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '0'	Hassan Haji (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '8 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User entered empty.	System	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User entered empty.	System	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:06
User entered empty.	System	13 Oct 2020 18:57:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
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: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:01:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:01:17
Data point term sent to Coder	System	13 Oct 2020 19:00:05
User entered 'Advil'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'headache'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '400'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'mg (mg)'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'as needed (PRN)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '7 Oct 2020'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '0'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '8 Oct 2020'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User entered empty.	System	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User entered empty.	System	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:13
User entered empty.	System	13 Oct 2020 18:59:59

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:02:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:02:20
Data point term sent to Coder User entered 'influenza vaccine'	System Hassan Haji (b) (4)	13 Oct 2020 19:02:06 13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'influenza'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '0.5'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'mL (mL)'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '6 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '0'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered '6 Oct 2020'	Hassan Haji (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User entered empty.	System	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User entered empty.	System	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:10
User entered empty.	System	13 Oct 2020 19:01:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 12:33:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 12:33:12
Data point term sent to Coder	System	21 Apr 2021 12:31:44
User entered 'Zosyn'	(b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Ruptured Appendix'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User entered empty.	System	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User entered empty.	System	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:17
User entered empty.	System	21 Apr 2021 12:30:50

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 12:47:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 12:47:06
Data point term sent to Coder	System	21 Apr 2021 12:36:48
User entered 'Ceftriaxone'	(b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Ruptured Appendix'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User entered empty.	System	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User entered empty.	System	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:21
User entered empty.	System	21 Apr 2021 12:36:43

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: CEFTIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 10:51:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 10:51:53
Data point term sent to Coder	System	21 Apr 2021 12:55:17
Query 'CDM-Coding: The trade name CEFTIN can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' canceled (Site from System).	Coder Import (b) (4)	21 Apr 2021 12:54:57
User opened query 'CDM-Coding: The trade name CEFTIN can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	21 Apr 2021 12:52:55
Data point term sent to Coder	System	21 Apr 2021 12:40:52
User entered 'Ceftin'	(b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Ruptured Appendix'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '500'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '01 Mar 2021' reason for change: Data Entry Error	System	21 Apr 2021 13:22:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 13:22:44
User entered '29 Feb 2021' (non-conformant).		
	System	21 Apr 2021 12:40:18
	(b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User entered '2'	System	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User entered '1'	System	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:28
User entered '804 (804)'	System	21 Apr 2021 12:40:18

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:45
Data point term sent to Coder	System	21 Apr 2021 13:25:39
User entered 'Metronidazole'	(b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Ruptured Appendix'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '500'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User entered '3'	System	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User entered '1'	System	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:34
User entered '804 (804)'	System	21 Apr 2021 13:24:48

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:45
Data point term sent to Coder	System	21 Apr 2021 13:26:40
User entered 'Metronidazole'	(b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Ruptured Appendix'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User entered empty.	System	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User entered empty.	System	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:30:39
User entered empty.	System	21 Apr 2021 13:26:24

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 14:29:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 14:29:58
Data point term sent to Coder	System	21 Apr 2021 13:29:41
User entered 'Shingrix Vaccine'	(b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Zoster prophylaxis'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0.5'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 13:28:57

US3742034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:29:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:17
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:40
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:22:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:22:43
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
User closed query 'Per CDM: Concomitant Procedures summary performed is Yes, however no data is present on Concomitant Procedures eCRF. Please review and update accordingly.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:40:42
' (Site from DM).		
Query 'Per CDM: Concomitant Procedures summary performed is Yes, however no data is present on Concomitant Procedures eCRF. Please review and update accordingly.	(b) (4), (b) (6)	12 Mar 2021 19:07:38
' answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:06:43
User opened query 'Per CDM: Concomitant Procedures summary performed is Yes, however no data is present on Concomitant Procedures eCRF. Please review and update accordingly.	(b) (4), (b) (6)	09 Mar 2021 19:43:44
' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:57:39
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 16:57:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:08:06
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Feb 2021 19:13:13

US3742034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:40
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	12 Apr 2021 14:23:46

US3742034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:40
User entered 'Laparoscopic Appendectomy'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:23:46

US3742034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:40
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:23:46

US3742034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:40
	(b) (4)	
User entered 'Appendicitis'	(b) (4), (b) (6)	12 Apr 2021 14:23:46

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered '17/Feb/2021 11:24'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:49

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)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:52
User entered '01/Mar/2021 11:10'	System	01 Mar 2021 16:10:33

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:53:32
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 16:10:33

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:52
User entered '04/Mar/2021 12:53'	System	04 Mar 2021 17:53:28

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:53:32
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 17:53:28

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
User entered '09/Mar/2021 12:08'	(b) (4) System	09 Mar 2021 17:08:04

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:07:00
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 17:08:04

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
User entered '06/Apr/2021 14:07'	(b) (4) System	06 Apr 2021 18:07:23

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:29:49

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)	13 Apr 2021 13:28:06
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:07:23

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
User entered '13/Apr/2021 09:28'	(b) (4) System	13 Apr 2021 13:28:01

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 13:28:06
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:28:01

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
User entered '13/Apr/2021 09:33'	(b) (4) System	13 Apr 2021 13:33:34

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 13:33:40
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:33:34

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered '21/Apr/2021 12:09'	(b) (4) System	21 Apr 2021 17:09:07

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:11:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:09:07

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'USA-US127-2021-MRNA-1273-P301000011'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:56:35
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:52
Un-reviewed for Safety.	System	08 Mar 2021 15:28:57
DataPoint Un-verified.	System	08 Mar 2021 15:28:57
Signature has been broken.	System	08 Mar 2021 15:28:57
User entered 'Yes (Y)'	System	08 Mar 2021 15:28:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Yes (Y)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'No (N)'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Karen'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Kotloff'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '685 W. Baltimore Street, HSF 480'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered 'Baltimore'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:23:54
User entered '21201'	System	17 Feb 2021 16:23:12

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:06:41
User entered 'US'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	28 Apr 2021 19:23:35
User entered '8'	System	21 Apr 2021 17:09:07
User entered '7'	System	13 Apr 2021 13:33:34
User entered '6'	System	13 Apr 2021 13:28:01
User entered '5'	System	06 Apr 2021 18:07:23
User entered '4'	System	09 Mar 2021 17:08:04
User entered '3'	System	04 Mar 2021 17:53:28
User entered '2'	System	01 Mar 2021 16:10:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:31:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 16:24:11

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	28 Apr 2021 23:34:06
User entered '28/Apr/2021 12:23'	(b) (4) System	28 Apr 2021 19:23:35

US3742034

Folder: SAE USA-US127-2021-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:29:49

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 signature succeeded.	Milagritos Tapia (b) (4)	28 Apr 2021 23:34:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:23:35