

US3742301 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

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US3742301

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:55:48

Generated On: 10 Jun 2021 09:31:42

[Participant ID](#)

US3742301

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

US3742301

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	45
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	True

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:41:10

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Date of Informed Consent (<i>dd MMM yyyy</i>)	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 17:41:10

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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 17:41:10

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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 17:41:10

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN MAY 2019
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)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:41:10

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Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	5 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	05 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:41:10

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Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2010
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)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Condition	ENDOMETRIALABLACION
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Condition	OBESITY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:19
Height (xxx.x)	63 in
Weight (xxx.x)	267.5 lb
BMI (xxx.x)	47.48458 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
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 17:41:10

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:41:10

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Date of assessment (*dd MMM yyyy*) 9 SEP 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 17:41:10

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	9 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:41:10

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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

WEEKLY CHURCH GROUP > 30 PEOPLE

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 17:41:10

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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 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 146105

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 17:41:10

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Height	ND - Not Done
Weight	ND - Not Done
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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:19
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	067 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 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 17:41:10

Generated On: 10 Jun 2021 09:31:42

Height	ND - Not Done
Weight	ND - Not Done
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)	09 SEP 2020
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 16:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 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 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:41:10

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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 17:41:10

Generated On: 10 Jun 2021 09:31:42

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 16:10 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 16:10

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 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	9 SEP 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:48	9 SEP 2020 14:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

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 09:31:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

09 SEP 2020 16:44

PC Open Date & Time

09 SEP 2020 16:30

PC Close Date & Time

09 SEP 2020 19:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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	09 SEP 2020 22:58
PC Open Date & Time	09 SEP 2020 19:55
PC Close Date & Time	10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

10 SEP 2020 12:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

11 SEP 2020 12:27

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

98.9 °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

12 SEP 2020 14:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

95.7 °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

13 SEP 2020 12:37

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

99.6 °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

14 SEP 2020 13:47

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 13:41

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:45

PC Open Date & Time

09 SEP 2020 16:30

PC Close Date & Time

09 SEP 2020 19:00

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

09 SEP 2020 22:59

PC Open Date & Time

09 SEP 2020 19:55

PC Close Date & Time

10 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

10 SEP 2020 12:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

11 SEP 2020 12:28

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

12 SEP 2020 14:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

13 SEP 2020 12:37

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

14 SEP 2020 13:47

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

15 SEP 2020 13:42

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 16:45
PC Open Date & Time	09 SEP 2020 16:30
PC Close Date & Time	09 SEP 2020 19:00

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 23:00
PC Open Date & Time	09 SEP 2020 19:55
PC Close Date & Time	10 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:04
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:38
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 13:49
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 13:42
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 16 SEP 2020 13:36

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

17 SEP 2020 12:57

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

18 SEP 2020 12:00

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 13:36

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:57

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:00

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 16:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 SEP 2020 13:37

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 12:58

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 12:00

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 13:37

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 12:58

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

16 SEP 2020 13:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	16 SEP 2020 12:00
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PC Close Date & Time	17 SEP 2020 11:59
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PC Time stamp	16 SEP 2020 13:37
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US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 13:37
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:57
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 12:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742301

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	VISIT2

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

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)	08 OCT 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 15:20
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

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)	08 OCT 2020
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 16:43
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

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) _____

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 16:13 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 16:13

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

US3742301

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 OCT 2020
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	08 OCT 2020 15:50

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Collection date (dd MMM yyyy)			08 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:54	08 OCT 2020 15:54
Nasopharyngeal Swab 2	No		

US3742301

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 17:12

PC Open Date & Time

08 OCT 2020 16:33

PC Close Date & Time

08 OCT 2020 19:03

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 OCT 2020 19:58

PC Close Date & Time

09 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

97.3 °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

09 OCT 2020 12:40

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 10 OCT 2020 12:17

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

11 OCT 2020 13:18

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 12 OCT 2020 12:30

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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 13 OCT 2020 17:06

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 12:28

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 17:13

PC Open Date & Time

08 OCT 2020 16:33

PC Close Date & Time

08 OCT 2020 19:03

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

08 OCT 2020 19:58

PC Close Date & Time

09 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

09 OCT 2020 12:41

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

10 OCT 2020 12:18

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

11 OCT 2020 13:19

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

12 OCT 2020 12:31

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

13 OCT 2020 17:07

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

14 OCT 2020 12:29

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 17:12
PC Open Date & Time	08 OCT 2020 16:33
PC Close Date & Time	08 OCT 2020 19:03

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 19:58

PC Close Date & Time

09 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:41
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 12:18
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 13:19
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 12:31
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 ☒

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US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 17:07
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 ☒

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 12:29
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 OCT 2020 13:30

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 12:04

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 OCT 2020 15:47

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 OCT 2020 13:30

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	16 OCT 2020 12:04
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PC Open Date & Time	16 OCT 2020 12:00
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PC Close Date & Time	17 OCT 2020 11:59
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US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 15:47

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 12:50

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	15 OCT 2020 12:00
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PC Close Date & Time	16 OCT 2020 11:59
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PC Time stamp	15 OCT 2020 13:30
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US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	16 OCT 2020 12:00
---------------------	-------------------

PC Close Date & Time	17 OCT 2020 11:59
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PC Time stamp	16 OCT 2020 12:04
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US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

PC Time stamp 17 OCT 2020 15:47

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 13:30
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 12:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 15:47
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3742301

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:40:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 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

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:41:11

Generated On: 10 Jun 2021 09:31:42

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) _____

US3742301

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3742301

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 NOV 2020
Collection time (00:00-23:59)	16:42 (24 HR)
Collection date and time (derived)	05 NOV 2020 16:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:41:10

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 11:59:02

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

16 NOV 2020 14:48:30

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	20 NOV 2020 12:33:13
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 10:41:01
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 00:02:15

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 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	11 DEC 2020 11:39:39
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

18 DEC 2020 14:40:47

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 10:52:10

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

01 JAN 2021 13:16:16

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

08 JAN 2021 11:13:36

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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	15 JAN 2021 07:54:57
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

22 JAN 2021 11:22:37

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 12:36:08

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 12:20:40

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

12 FEB 2021 16:21:56

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

19 FEB 2021 14:20:23

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 17:15:02

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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	05 MAR 2021 12:01:10
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

12 MAR 2021 12:24:55

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

19 MAR 2021 17:09:39

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

26 MAR 2021 14:57:14

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

02 APR 2021 20:32:10

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

09 APR 2021 12:45:00

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

16 APR 2021 14:17:53

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

23 APR 2021 12:44:55

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

30 APR 2021 15:47:26

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	05 OCT 2021 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
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Patient Cloud Close Date & Time	05 APR 2022 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
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Patient Cloud Close Date & Time	19 APR 2022 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
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Patient Cloud Close Date & Time	19 JUL 2022 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 <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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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="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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3742301

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:31:42

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		05 MAR 2021 12:01:43

US3742301

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

NOW REPORTS SHE WAS
ADMITTED FOR "TWISTED
INTESTINES" AND HAD AN
EMERGENCY SURGERY TO
CORRECT ISSUE - WAS
ADMITTED AND DISCHARGED.
NO CHANGES TO MEDICATION
PER PARTICIPANT.

US3742301

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

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) _____

US3742301

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

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.

US3742301

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

25 MAR 2021 12:20

US3742301

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

US3742301

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742301

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:42

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"/>

US3742301

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:31:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742301

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
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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
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US3742301

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:46:10

Generated On: 10 Jun 2021 09:31:42

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3742301

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3742301

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:10
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:03
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3742301

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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) _____

US3742301

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:29

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

US3742301

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	10:53 (24 HR)
Collection date and time (derived)	14 JAN 2021 10:53

US3742301

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:54
Collection Date and Time (derived)	14 JAN 2021 10:54

US3742301

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742301

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3742301

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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)	11 FEB 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 10:55
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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)	11 FEB 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 11:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3742301

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 FEB 2021
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)	

US3742301

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 11:13

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

US3742301

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

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

US3742301

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:55:50

Generated On: 10 Jun 2021 09:31:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742301

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	OLD57

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

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) _____

US3742301

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:35:53

Generated On: 10 Jun 2021 09:31:42

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.

US3742301

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:35:52

Generated On: 10 Jun 2021 09:31:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	12:20 (24 HR)
Collection date and time (derived)	25 MAR 2021 12:20

US3742301

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 21:34:29

Generated On: 10 Jun 2021 09:31:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	9 OCT 2020
Start time (00:00-23:59)	12:41 (24 HR)
AE start date and time (derived)	9 OCT 2020 12:41
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	16 OCT 2020 12:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

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 type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID	
Adverse event	MUSCLE ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 OCT 2020
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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
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)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID

Adverse event

GENERALIZED JOINT PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 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)

17 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID

Adverse event

URINARY TRACT INFECTION

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)

26 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)

03 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 21:48:33

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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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID	USA-US127-2021-MRNA-1273-P30 1000009
Adverse event	INTERNAL HERNIA
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)	16 JAN 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)	22 JAN 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 checked="" type="radio"/> Grade 4 <input 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	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	22 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 21:48:33

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Number of Days in ICU	
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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

CONTACT PARTICIPANT
TODAY FOR DAY 149 SAFETY
AND SHE INFORMED US THAT
SHE HAD BEEN ADMITTED
WITH "TWISTED INTESTINES".
SHE HAD SURGERY WITH
REPORTEDLY BOWEL
RESECTION RESECTION.
ADMITTED 16JAN2021 TO
22JAN2021.
ADDENDUM - ACCORDING TO
HOSPITAL RECORDS
PARTICIPANT DID NOT HAVE
HAVE BOWEL RESECTION BUT
HAD A LAPAROSCOPIC
INTERNAL HERNIA REPAIR.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 SEP 2020
Start time (00:00-23:59)	12:29 (24 HR)
AE start date and time (derived)	10 SEP 2020 12:29
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 SEP 2020
End time (00:00-23:59)	12:57 (24 HR)
AE End Date and Time (derived)	17 SEP 2020 12:57
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 21:48:33

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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	True
Concomitant Medication	False
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)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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 SEP 2020
Start time (00:00-23:59)	23:00 (24 HR)
AE start date and time (derived)	09 SEP 2020 23:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	18 SEP 2020 12:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Apr 2021 21:48:33

Generated On: 10 Jun 2021 09:31:42

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	True
Concomitant Medication	False
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)	_____

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Name of Medication LSINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 17:55:49

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	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 MAY 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 (2)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

	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 JUL 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 (3)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

Name of Medication IRON

Prophylaxis Yes ☐
No ☒

Indication MENORRHAGIA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 17:55:49

Generated On: 10 Jun 2021 09:31:42

	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 2017	
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"/>

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:35:52

Generated On: 10 Jun 2021 09:31:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 21:46:10

Generated On: 10 Jun 2021 09:31:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 JAN 2021	LAPAROSCOPY INTERNAL HERNIA REPAIR	Adverse Event	

US3742301

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:31:42

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

US3742301

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:31:42

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 ☐

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 21:46:11

Generated On: 10 Jun 2021 09:31:42

SAEID	USA-US127-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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)	4

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 21:46:11

Generated On: 10 Jun 2021 09:31:42

SAEID	USA-US127-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	04/FEB/2021 10:06
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

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 21:46:11

Generated On: 10 Jun 2021 09:31:42

SAEID	USA-US127-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	24/FEB/2021 10:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 21:46:11

Generated On: 10 Jun 2021 09:31:42

SAEID	USA-US127-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 08:56
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

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 21:46:11

Generated On: 10 Jun 2021 09:31:42

SAEID	USA-US127-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 15:53
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

Audit

US3742301 (Prod: University of Maryland School of Medicine)

US3742301

Form: Participant Creation

Generated On: 10 Jun 2021 09:31:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US3742301'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:54:38

US3742301

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:14:05

US3742301

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:54:39

US3742301

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	09 Sep 2020 20:14:05

US3742301

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'SCRN'	System	09 Sep 2020 20:14:05

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:54:40

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '45'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'YEARS'	System	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '46'	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Female (F)'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'I'	Sherry McCammon (b) (4)	09 Sep 2020 20:17:50

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Sep 2020'	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2020'	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Amendment 3 (3)'	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:54:39

US3742301

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'I'	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:18:13

US3742301

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:31:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 12:57:20

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:01:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:01:32
Data point term sent to Coder	System	11 Sep 2020 13:00:34
User entered 'hypertension'	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'UN May 2019'	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'May 2019'	System	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2019'	System	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	11 Sep 2020 12:59:42

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:36
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:05:05
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:52:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:04:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:04:32
Data point term sent to Coder	System	11 Sep 2020 13:03:47
User entered 'gastric bypass'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '5 Aug 2019'	Hassan Haji (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:04:57
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '05 Aug 2019' reason for change: New Information	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:04:57
User entered empty.	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Aug 2019'	System	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2019'	System	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Aug 2019'	System	27 Oct 2020 20:04:57
User entered empty.	System	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2019'	System	27 Oct 2020 20:04:57
User entered empty.	System	11 Sep 2020 13:03:32

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:11:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:11:39
Data point term sent to Coder	System	11 Sep 2020 13:11:10
User entered 'menorrhagia'	Hassan Haji (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22."' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 11:41:02
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22."' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:07:48
User entered 'UN UNK 2010' reason for change: Per Query Resolution	(b) (4), (b) (6)	27 Oct 2020 20:07:43
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22."' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 18:05:10
User entered '9 Sep 2020'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Jan 2010'	System	27 Oct 2020 20:07:43
User entered 'Sep 2020'	System	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2010'	System	27 Oct 2020 20:07:43
User entered '2020'	System	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	11 Sep 2020 13:10:41

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Endometrial ablation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Oct 2020 05:33:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:33:33
Data point term sent to Coder	System	20 Oct 2020 19:03:51
User entered 'Endometrialablation'	(b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'UN Oct 2019'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'UN Oct 2019'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Oct 2019'	System	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2019'	System	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'Oct 2019'	System	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '2019'	System	20 Oct 2020 19:02:55

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:43:46
Data point term sent to Coder	System	23 Dec 2020 18:42:23
User entered 'obesity'	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'I'	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Kaitlin Mason (b) (4)	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	23 Dec 2020 18:41:27

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 Sep 2020'	(b) (4) Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 14:04:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	18 Sep 2020 14:04:29
User entered '14:19' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:29
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 14:04:00
User entered empty.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '09 Sep 2020 14:19'	System	18 Sep 2020 14:04:29
User entered empty.	System	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '63' in	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00
DataPoint set to visible.	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '267.5' lb	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00
DataPoint set to visible.	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '47.48458'	System	18 Sep 2020 14:04:00
DataPoint set to visible.	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'kg/m2'	System	18 Sep 2020 14:04:00
DataPoint set to visible.	System	09 Sep 2020 20:18:53

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'bpm'	System	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'breaths/min'	System	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	18 Sep 2020 14:04:00

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55

US3742301

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55

US3742301

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:19:20

US3742301

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:19:20

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	(b) (4)	20 Oct 2020 19:00:31
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	20 Oct 2020 18:59:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	20 Oct 2020 18:59:04
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27
	(b) (4)	

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:05:05
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:59:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 18:59:04
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:43:00
User entered 'Surgically sterile (SURGICALLY STERILE)'	Sherry McCammon (b) (4) (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:00:31
User entered 'UN Oct 2019'	Sherry McCammon (b) (4) (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:23:27

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	20 Oct 2020 19:01:09

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'weekly church group > 30 people'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'I'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '0'	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:20:45

US3742301

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:21:09

US3742301

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Dec 2020 15:01:16
User entered '9 Sep 2020'	(b) (4)	
	Sherry McCammon (b) (4)	09 Sep 2020 20:21:09
	(b) (4)	

US3742301

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	09 Sep 2020 20:21:09

US3742301

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'VISIT1'	System	09 Sep 2020 20:21:09

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:30:12

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '146105'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:30:12

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:30:12

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:32:19

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:32:19

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'per CDM: obesity is marked as yes, but is not present on the medical history form, please clarify or reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 00:04:29
Query 'per CDM: obesity is marked as yes, but is not present on the medical history form, please clarify or reconcile' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	23 Dec 2020 18:40:58
User opened query 'per CDM: obesity is marked as yes, but is not present on the medical history form, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 19:35:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:32:19

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:32:19

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:32:19

US3742301

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:42

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:59:46
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'UPDATED' (Site from DM).	Sherry McCammon (b) (4)	09 Dec 2020 15:03:02
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Dec 2020 15:02:47
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:54:11
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:51:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:51:25

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:49:27
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:37:56
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:58:57
User entered '63.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:37:56
User entered '267.5' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:49:27
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:37:56
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:58:57
User entered '63.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:37:56
User entered '267.5' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:37:56
User entered '9 Sep 2020'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '14:19'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '09 Sep 2020 14:19'	System	22 Sep 2020 15:37:56
User entered '9 Sep 2020 14:19'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '098.5' F	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '067'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'bpm'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '14'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'breaths/min'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '116'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '073'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:49:27
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:37:56
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:58:57
User entered '63.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:37:56
User entered '267.5' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:37:56
User entered '9 Sep 2020'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16:40'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '09 Sep 2020 16:40'	System	22 Sep 2020 15:37:56
User entered '9 Sep 2020 16:40'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '98.3' F	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:41:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '068'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'bpm'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '18'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'breaths/min'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '122'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '078'	Hassan Haji (b) (4)	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	11 Sep 2020 13:41:09

US3742301

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Physical examination 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. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 12:27:59
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Physical examination 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. Thank you.' answered with 'UPDATED' (Site from DM).	Sherry McCammon (b) (4)	09 Dec 2020 15:02:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 15:02:01
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Physical examination 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. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:12:49
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:21:16

US3742301

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Dec 2020 15:02:01
User entered '09 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Dec 2020 14:18:22
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:21:16

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Per CDM : Please enter YES/NO in this field.' (Site from DM).	(b) (4)	01 Dec 2020 09:07:29
Query 'Per CDM : Please enter YES/NO in this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 17:13:19
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Nov 2020 17:13:12
User opened query 'Per CDM : Please enter YES/NO in this field.' (Site from DM).	(b) (4)	30 Nov 2020 09:12:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 12:28:08
	Kaitlin Mason (b) (4)	
	(b) (4)	

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered empty.	System	17 Nov 2020 12:28:08

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16:10'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '9 Sep 2020 16:10'	System	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'ONCE'	System	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 20:29:56

US3742301

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:21

US3742301

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:21

US3742301

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '14:50'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:21

US3742301

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '9 Sep 2020 14:50'	System	09 Sep 2020 20:22:21

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '9 Sep 2020'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '14:48'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '9 Sep 2020 14:48'	System	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered empty.	System	09 Sep 2020 20:22:08

US3742301

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:41:47

US3742301

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	11 Sep 2020 13:41:47

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '74c590b5-cd4a-4499-860b-62a53e957ff8'	System	09 Sep 2020 20:44:31
User entered 'Yes (Y)'	System	09 Sep 2020 20:44:31

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:12', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '74c590b5-cd4a-4499-860b-62a53e957ff8' User entered '98.3'	System	09 Sep 2020 20:44:31
	System	09 Sep 2020 20:44:31

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:20', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '74c590b5-cd4a-4499-860b-62a53e957ff8'	System	09 Sep 2020 20:44:31
User entered 'No (N)'	System	09 Sep 2020 20:44:31

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:26', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '74c590b5-cd4a-4499-860b-62a53e957ff8' User entered '09 Sep 2020 16:44'	System	09 Sep 2020 20:44:31
	System	09 Sep 2020 20:44:31

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 16:30'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:58:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cf5c7ae5-6017-435a-a788-c715d7a19ba8' User entered 'Yes (Y)'	System	10 Sep 2020 02:59:02
	System	10 Sep 2020 02:59:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:58:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cf5c7ae5-6017-435a-a788-c715d7a19ba8' User entered '97.2'	System	10 Sep 2020 02:59:02
	System	10 Sep 2020 02:59:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:58:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cf5c7ae5-6017-435a-a788-c715d7a19ba8' User entered 'No (N)'	System	10 Sep 2020 02:59:02
	System	10 Sep 2020 02:59:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:58:58', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cf5c7ae5-6017-435a-a788-c715d7a19ba8' User entered '09 Sep 2020 22:58'	System	10 Sep 2020 02:59:02
	System	10 Sep 2020 02:59:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:55'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 2'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:26:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9' User entered 'No (N)'	System	10 Sep 2020 16:27:26
	System	10 Sep 2020 16:27:26

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:07', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9'	System	10 Sep 2020 16:27:26
User entered 'Yes (Y)'	System	10 Sep 2020 16:27:26

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:26:54', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9' User entered '0'	System	10 Sep 2020 16:27:26
	System	10 Sep 2020 16:27:26

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Pt denies taking medication during day 8 call ' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 11:13:24
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:26:54', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9' User entered '1'	Kaitlin Mason (b) (4) (b) (4)	18 Sep 2020 14:08:58
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Sep 2020 16:27:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:26:54', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9' User entered '1'	System	10 Sep 2020 16:27:26
User entered '1'	System	10 Sep 2020 16:27:26

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '49f462dc-9fb2-410d-9cae-a7ab647a94b9' User entered '10 Sep 2020 12:27'	System	10 Sep 2020 16:27:26
	System	10 Sep 2020 16:27:26

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 3'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '03db44e9-9dfb-4b3b-859e-8e6e1c220a2b' User entered 'Yes (Y)'	System	11 Sep 2020 16:27:49
	System	11 Sep 2020 16:27:49

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '03db44e9-9dfb-4b3b-859e-8e6e1c220a2b' User entered '97.0'	System	11 Sep 2020 16:27:49
	System	11 Sep 2020 16:27:49

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:31', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '03db44e9-9dfb-4b3b-859e-8e6e1c220a2b' User entered 'No (N)'	System	11 Sep 2020 16:27:49
	System	11 Sep 2020 16:27:49

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '03db44e9-9dfb-4b3b-859e-8e6e1c220a2b' User entered '11 Sep 2020 12:27'	System	11 Sep 2020 16:27:49
	System	11 Sep 2020 16:27:49

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 4'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:03:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9eb85ff7-8109-4981-9ca2-a1d9bb6679fa' User entered 'Yes (Y)'	System	12 Sep 2020 18:03:51
	System	12 Sep 2020 18:03:51

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:03:39', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9eb85ff7-8109-4981-9ca2-a1d9bb6679fa' User entered '98.9'	System	12 Sep 2020 18:03:51
	System	12 Sep 2020 18:03:51

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:03:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9eb85ff7-8109-4981-9ca2-a1d9bb6679fa' User entered 'No (N)'	System	12 Sep 2020 18:03:51
	System	12 Sep 2020 18:03:51

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:03:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9eb85ff7-8109-4981-9ca2-a1d9bb6679fa' User entered '12 Sep 2020 14:03'	System	12 Sep 2020 18:03:51
	System	12 Sep 2020 18:03:51

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 5'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:36:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ce0199c-0c9f-4b83-a119-5e9700b661cf' User entered 'Yes (Y)'	System	13 Sep 2020 16:37:05
	System	13 Sep 2020 16:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:36:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ce0199c-0c9f-4b83-a119-5e9700b661cf' User entered '95.7'	System	13 Sep 2020 16:37:05
	System	13 Sep 2020 16:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:36:58', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ce0199c-0c9f-4b83-a119-5e9700b661cf' User entered 'No (N)'	System	13 Sep 2020 16:37:05
	System	13 Sep 2020 16:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:02', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ce0199c-0c9f-4b83-a119-5e9700b661cf' User entered '13 Sep 2020 12:37'	System	13 Sep 2020 16:37:05
	System	13 Sep 2020 16:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 6'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '310ca83f-e611-4375-8c50-30c2223e8437' User entered 'Yes (Y)'	System	14 Sep 2020 17:47:28
	System	14 Sep 2020 17:47:28

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '310ca83f-e611-4375-8c50-30c2223e8437' User entered '99.6'	System	14 Sep 2020 17:47:28
	System	14 Sep 2020 17:47:28

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:19', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '310ca83f-e611-4375-8c50-30c2223e8437'	System	14 Sep 2020 17:47:28
User entered 'No (N)'	System	14 Sep 2020 17:47:28

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '310ca83f-e611-4375-8c50-30c2223e8437' User entered '14 Sep 2020 13:47'	System	14 Sep 2020 17:47:28
	System	14 Sep 2020 17:47:28

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 7'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:41:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9c8fc08f-2be6-48ab-bfce-8295f6465031' User entered 'Yes (Y)'	System	15 Sep 2020 17:42:02
	System	15 Sep 2020 17:42:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:41:46', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9c8fc08f-2be6-48ab-bfce-8295f6465031' User entered '97.4'	System	15 Sep 2020 17:42:02
	System	15 Sep 2020 17:42:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:41:53', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9c8fc08f-2be6-48ab-bfce-8295f6465031' User entered 'No (N)'	System	15 Sep 2020 17:42:02
	System	15 Sep 2020 17:42:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:41:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9c8fc08f-2be6-48ab-bfce-8295f6465031' User entered '15 Sep 2020 13:41'	System	15 Sep 2020 17:42:02
	System	15 Sep 2020 17:42:02

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:46', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd96746eb-a680-4c48-ba2a-02bf2e861533'	System	09 Sep 2020 20:45:11
User entered 'None (1)'	System	09 Sep 2020 20:45:11

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:44:53', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd96746eb-a680-4c48-ba2a-02bf2e861533'	System	09 Sep 2020 20:45:11
User entered 'No (N)'	System	09 Sep 2020 20:45:11

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd96746eb-a680-4c48-ba2a-02bf2e861533'	System	09 Sep 2020 20:45:11
User entered 'No (N)'	System	09 Sep 2020 20:45:11

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd96746eb-a680-4c48-ba2a-02bf2e861533'	System	09 Sep 2020 20:45:11
User entered 'None (1)'	System	09 Sep 2020 20:45:11

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd96746eb-a680-4c48-ba2a-02bf2e861533'	System	09 Sep 2020 20:45:11
User entered '09 Sep 2020 16:45'	System	09 Sep 2020 20:45:11

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 16:30'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e81280ed-0d78-40de-8f6c-66e78894970a' User entered 'None (1)'	System	10 Sep 2020 02:59:41
	System	10 Sep 2020 02:59:41

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e81280ed-0d78-40de-8f6c-66e78894970a' User entered 'No (N)'	System	10 Sep 2020 02:59:41
	System	10 Sep 2020 02:59:41

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:21', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e81280ed-0d78-40de-8f6c-66e78894970a' User entered 'No (N)'	System	10 Sep 2020 02:59:41
	System	10 Sep 2020 02:59:41

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e81280ed-0d78-40de-8f6c-66e78894970a' User entered 'None (1)'	System	10 Sep 2020 02:59:41
	System	10 Sep 2020 02:59:41

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:38', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e81280ed-0d78-40de-8f6c-66e78894970a' User entered '09 Sep 2020 22:59'	System	10 Sep 2020 02:59:41
	System	10 Sep 2020 02:59:41

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:55'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 2'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ca4955e6-9760-46b4-a4c0-04859ffa82a8'	System	10 Sep 2020 16:28:02
User entered 'None (1)'	System	10 Sep 2020 16:28:02

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:38', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ca4955e6-9760-46b4-a4c0-04859ffa82a8' User entered 'No (N)'	System	10 Sep 2020 16:28:02
	System	10 Sep 2020 16:28:02

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ca4955e6-9760-46b4-a4c0-04859ffa82a8' User entered 'No (N)'	System	10 Sep 2020 16:28:02
	System	10 Sep 2020 16:28:02

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ca4955e6-9760-46b4-a4c0-04859ffa82a8' User entered 'None (1)'	System	10 Sep 2020 16:28:02
	System	10 Sep 2020 16:28:02

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:27:57', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ca4955e6-9760-46b4-a4c0-04859ffa82a8' User entered '10 Sep 2020 12:27'	System	10 Sep 2020 16:28:02
	System	10 Sep 2020 16:28:02

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 3'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9b69de45-452d-4e48-967b-10f376479062'	System	11 Sep 2020 16:28:13
User entered 'None (1)'	System	11 Sep 2020 16:28:13

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:27:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9b69de45-452d-4e48-967b-10f376479062'	System	11 Sep 2020 16:28:13
User entered 'No (N)'	System	11 Sep 2020 16:28:13

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9b69de45-452d-4e48-967b-10f376479062'	System	11 Sep 2020 16:28:13
User entered 'No (N)'	System	11 Sep 2020 16:28:13

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:07', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9b69de45-452d-4e48-967b-10f376479062'	System	11 Sep 2020 16:28:13
User entered 'None (1)'	System	11 Sep 2020 16:28:13

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9b69de45-452d-4e48-967b-10f376479062' User entered '11 Sep 2020 12:28'	System	11 Sep 2020 16:28:13
	System	11 Sep 2020 16:28:13

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 4'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:03:54', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f435e1f7-a4aa-44f2-a953-afd9d10a6156'	System	12 Sep 2020 18:04:16
User entered 'None (1)'	System	12 Sep 2020 18:04:16

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f435e1f7-a4aa-44f2-a953-afd9d10a6156'	System	12 Sep 2020 18:04:16
User entered 'No (N)'	System	12 Sep 2020 18:04:16

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:04', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f435e1f7-a4aa-44f2-a953-afd9d10a6156'	System	12 Sep 2020 18:04:16
User entered 'No (N)'	System	12 Sep 2020 18:04:16

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f435e1f7-a4aa-44f2-a953-afd9d10a6156'	System	12 Sep 2020 18:04:16
User entered 'None (1)'	System	12 Sep 2020 18:04:16

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f435e1f7-a4aa-44f2-a953-afd9d10a6156'	System	12 Sep 2020 18:04:16
User entered '12 Sep 2020 14:04'	System	12 Sep 2020 18:04:16

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 5'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:10', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6646b361-8ce4-4f82-9bda-a43286b62b55'	System	13 Sep 2020 16:37:29
User entered 'None (1)'	System	13 Sep 2020 16:37:29

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6646b361-8ce4-4f82-9bda-a43286b62b55'	System	13 Sep 2020 16:37:29
User entered 'No (N)'	System	13 Sep 2020 16:37:29

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:19', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6646b361-8ce4-4f82-9bda-a43286b62b55'	System	13 Sep 2020 16:37:29
User entered 'No (N)'	System	13 Sep 2020 16:37:29

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6646b361-8ce4-4f82-9bda-a43286b62b55'	System	13 Sep 2020 16:37:29
User entered 'None (1)'	System	13 Sep 2020 16:37:29

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6646b361-8ce4-4f82-9bda-a43286b62b55' User entered '13 Sep 2020 12:37'	System	13 Sep 2020 16:37:29
	System	13 Sep 2020 16:37:29

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 6'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ff974136-211c-4137-9e30-49c33435c680'	System	14 Sep 2020 17:47:51
User entered 'None (1)'	System	14 Sep 2020 17:47:51

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ff974136-211c-4137-9e30-49c33435c680' User entered 'No (N)'	System	14 Sep 2020 17:47:51
	System	14 Sep 2020 17:47:51

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ff974136-211c-4137-9e30-49c33435c680' User entered 'No (N)'	System	14 Sep 2020 17:47:51
	System	14 Sep 2020 17:47:51

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:41', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ff974136-211c-4137-9e30-49c33435c680' User entered 'None (1)'	System	14 Sep 2020 17:47:51
	System	14 Sep 2020 17:47:51

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ff974136-211c-4137-9e30-49c33435c680' User entered '14 Sep 2020 13:47'	System	14 Sep 2020 17:47:51
	System	14 Sep 2020 17:47:51

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 7'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '59fee7cc-485a-43cb-8314-dfaf938f2db2'	System	15 Sep 2020 17:42:17
User entered 'None (1)'	System	15 Sep 2020 17:42:17

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:06', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '59fee7cc-485a-43cb-8314-dfaf938f2db2'	System	15 Sep 2020 17:42:17
User entered 'No (N)'	System	15 Sep 2020 17:42:17

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '59fee7cc-485a-43cb-8314-dfaf938f2db2'	System	15 Sep 2020 17:42:17
User entered 'No (N)'	System	15 Sep 2020 17:42:17

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '59fee7cc-485a-43cb-8314-dfaf938f2db2'	System	15 Sep 2020 17:42:17
User entered 'None (1)'	System	15 Sep 2020 17:42:17

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '59fee7cc-485a-43cb-8314-dfaf938f2db2'	System	15 Sep 2020 17:42:17
User entered '15 Sep 2020 13:42'	System	15 Sep 2020 17:42:17

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:20', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:28', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'None (0)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:46', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered 'No (N)'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T16:45:50', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1dc1185a-57f5-4654-9fa2-863b7ef1a9eb' User entered '09 Sep 2020 16:45'	System	09 Sep 2020 20:45:53
	System	09 Sep 2020 20:45:53

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 16:30'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T22:59:53', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered 'None (0)'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:04', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff'	System	10 Sep 2020 03:00:54
User entered 'No interference with activity (1)'	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered 'None (0)'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:21', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered 'None (0)'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:28', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered 'None (0)'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff'	System	10 Sep 2020 03:00:54
User entered 'No interference with activity (1)'	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered 'No (N)'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-09T23:00:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4e1b04fb-b3c3-4dac-b621-ce5e0eb31fff' User entered '09 Sep 2020 23:00'	System	10 Sep 2020 03:00:54
	System	10 Sep 2020 03:00:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Sep 2020 19:55'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 2'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68'	System	10 Sep 2020 16:29:07
User entered 'No interference with activity (1)'	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:12', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68'	System	10 Sep 2020 16:29:07
User entered 'No interference with activity (1)'	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered 'None (0)'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:26', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered 'None (0)'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:30', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered 'None (0)'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered 'None (0)'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:28:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered 'No (N)'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-10T12:29:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4fec1c8-6c5a-440e-8e57-5897bd971d68' User entered '10 Sep 2020 12:29'	System	10 Sep 2020 16:29:07
	System	10 Sep 2020 16:29:07

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 3'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'No interference with activity (1)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'No interference with activity (1)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:30', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'None (0)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:36', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'No interference with activity (1)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'None (0)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'No interference with activity (1)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:28:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered 'No (N)'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-11T12:29:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '53a595dd-de99-41da-8c11-a81d549e8a0f' User entered '11 Sep 2020 12:29'	System	11 Sep 2020 16:29:08
	System	11 Sep 2020 16:29:08

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 4'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:21', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323'	System	12 Sep 2020 18:04:54
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323'	System	12 Sep 2020 18:04:54
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323' User entered 'None (0)'	System	12 Sep 2020 18:04:54
	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323'	System	12 Sep 2020 18:04:54
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:41', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323' User entered 'None (0)'	System	12 Sep 2020 18:04:54
	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323'	System	12 Sep 2020 18:04:54
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323' User entered 'No (N)'	System	12 Sep 2020 18:04:54
	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-12T14:04:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c88bdcdf-b4d2-4ed0-94f9-136ae12b9323' User entered '12 Sep 2020 14:04'	System	12 Sep 2020 18:04:54
	System	12 Sep 2020 18:04:54

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 5'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc'	System	13 Sep 2020 16:38:10
User entered 'No interference with activity (1)'	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc'	System	13 Sep 2020 16:38:10
User entered 'No interference with activity (1)'	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc' User entered 'None (0)'	System	13 Sep 2020 16:38:10
	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc'	System	13 Sep 2020 16:38:10
User entered 'No interference with activity (1)'	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc' User entered 'None (0)'	System	13 Sep 2020 16:38:10
	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:37:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc'	System	13 Sep 2020 16:38:10
User entered 'No interference with activity (1)'	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:38:02', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc' User entered 'No (N)'	System	13 Sep 2020 16:38:10
	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-13T12:38:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec2cec8c-a66b-44f1-b11c-0cb4bd22f7bc' User entered '13 Sep 2020 12:38'	System	13 Sep 2020 16:38:10
	System	13 Sep 2020 16:38:10

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 6'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:47:55', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab'	System	14 Sep 2020 17:49:12
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:48:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered 'None (0)'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:48:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered 'None (0)'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:48:12', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered 'None (0)'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:48:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered 'None (0)'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:48:22', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab'	System	14 Sep 2020 17:49:12
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:49:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered 'No (N)'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-14T13:49:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '393e9c7e-2107-4ae2-94be-901c8b3b91ab' User entered '14 Sep 2020 13:49'	System	14 Sep 2020 17:49:12
	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 7'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:19', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:26', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a'	System	15 Sep 2020 17:43:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a' User entered 'No (N)'	System	15 Sep 2020 17:43:01
	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-15T13:42:58', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '8b5b4965-6c35-4d1b-866d-ab8a9dc5545a' User entered '15 Sep 2020 13:42'	System	15 Sep 2020 17:43:01
	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Sep 2020 17:49:12
User entered 'Day 8'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:36:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ddde009a-11ca-4ac5-948f-deb8614ae5b8'	System	16 Sep 2020 17:36:43
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:36:39', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ddde009a-11ca-4ac5-948f-deb8614ae5b8' User entered '16 Sep 2020 13:36'	System	16 Sep 2020 17:36:43
	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 9'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0fdb30df-47a7-4382-918e-0eb2d52f19e1'	System	17 Sep 2020 16:57:22
User entered 'No interference with activity (1)'	System	17 Sep 2020 16:57:22

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:21', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0fdb30df-47a7-4382-918e-0eb2d52f19e1' User entered '17 Sep 2020 12:57'	System	17 Sep 2020 16:57:22
	System	17 Sep 2020 16:57:22

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	16 Sep 2020 17:36:43
User entered 'Day 10'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '619a455b-2335-4f20-9b18-9b1519d3896f' User entered 'None (0)'	System	18 Sep 2020 16:00:58
	System	18 Sep 2020 16:00:58

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:39', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '619a455b-2335-4f20-9b18-9b1519d3896f' User entered '18 Sep 2020 12:00'	System	18 Sep 2020 16:00:58
	System	18 Sep 2020 16:00:58

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 8'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:36:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a2701d9a-f34e-4912-b8c0-5dd9a0d350cf' User entered 'No interference with activity (1)'	System	16 Sep 2020 17:36:49
	System	16 Sep 2020 17:36:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:36:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a2701d9a-f34e-4912-b8c0-5dd9a0d350cf' User entered '16 Sep 2020 13:36'	System	16 Sep 2020 17:36:49
	System	16 Sep 2020 17:36:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 9'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '483430cd-27ba-4368-baf4-04f862436589'	System	17 Sep 2020 16:57:49
User entered 'No interference with activity (1)'	System	17 Sep 2020 16:57:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '483430cd-27ba-4368-baf4-04f862436589' User entered '17 Sep 2020 12:57'	System	17 Sep 2020 16:57:49
	System	17 Sep 2020 16:57:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	16 Sep 2020 17:36:49
User entered 'Day 10'	System	16 Sep 2020 17:36:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6b0438cf-6580-4a6e-ba8d-1fc290d6a0de'	System	18 Sep 2020 16:01:17
User entered 'No interference with activity (1)'	System	18 Sep 2020 16:01:17

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:50', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6b0438cf-6580-4a6e-ba8d-1fc290d6a0de' User entered '18 Sep 2020 12:00'	System	18 Sep 2020 16:01:17
	System	18 Sep 2020 16:01:17

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:36:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:36:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	17 Sep 2020 16:57:49
User entered 'Day 11'	System	17 Sep 2020 16:57:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-19T16:16:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4fefdfab-ee17-4d6a-99f0-926a2f92d80c' User entered 'None (0)'	System	19 Sep 2020 20:16:38
	System	19 Sep 2020 20:16:38

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-19T16:16:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4fefdfab-ee17-4d6a-99f0-926a2f92d80c' User entered '19 Sep 2020 16:16'	System	19 Sep 2020 20:16:38
	System	19 Sep 2020 20:16:38

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:57:49

US3742301

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:57:49

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 8'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:36:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '84cb1c31-5567-487d-9feb-7b8227b095ee'	System	16 Sep 2020 17:37:05
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '84cb1c31-5567-487d-9feb-7b8227b095ee' User entered '16 Sep 2020 13:37'	System	16 Sep 2020 17:37:05
	System	16 Sep 2020 17:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 9'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:58:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '78a93841-15bf-4380-a076-4f9bbc99a21e' User entered 'No interference with activity (1)'	System	17 Sep 2020 16:58:17
	System	17 Sep 2020 16:58:17

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:58:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '78a93841-15bf-4380-a076-4f9bbc99a21e' User entered '17 Sep 2020 12:58'	System	17 Sep 2020 16:58:17
	System	17 Sep 2020 16:58:17

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	16 Sep 2020 17:37:05
User entered 'Day 10'	System	16 Sep 2020 17:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd60ef9c5-21b6-4b96-88f1-7768133e9020' User entered 'None (0)'	System	18 Sep 2020 16:01:31
	System	18 Sep 2020 16:01:31

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:00:58', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd60ef9c5-21b6-4b96-88f1-7768133e9020' User entered '18 Sep 2020 12:00'	System	18 Sep 2020 16:01:31
	System	18 Sep 2020 16:01:31

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:37:05

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 8'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:06', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f2458deb-58ba-48c4-a9a9-87299562518a'	System	16 Sep 2020 17:37:13
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:37:13

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f2458deb-58ba-48c4-a9a9-87299562518a' User entered '16 Sep 2020 13:37'	System	16 Sep 2020 17:37:13
	System	16 Sep 2020 17:37:13

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 9'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:58:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1b4549d0-5ad5-44c9-a690-d228ab9a6b47' User entered 'None (0)'	System	17 Sep 2020 16:58:39
	System	17 Sep 2020 16:58:39

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:58:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1b4549d0-5ad5-44c9-a690-d228ab9a6b47' User entered '17 Sep 2020 12:58'	System	17 Sep 2020 16:58:39
	System	17 Sep 2020 16:58:39

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 8'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '52e04fb6-f2ba-4dc3-9c9d-2d1b877fe8b5' User entered 'None (0)'	System	16 Sep 2020 17:37:20
	System	16 Sep 2020 17:37:20

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '52e04fb6-f2ba-4dc3-9c9d-2d1b877fe8b5'	System	16 Sep 2020 17:37:20
User entered '16 Sep 2020 13:37'	System	16 Sep 2020 17:37:20

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Sep 2020 17:49:12
User entered 'Day 8'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:25', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f75adb31-d418-4809-99ac-08f7d4ace4d6' User entered 'None (0)'	System	16 Sep 2020 17:37:39
	System	16 Sep 2020 17:37:39

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f75adb31-d418-4809-99ac-08f7d4ace4d6' User entered '16 Sep 2020 13:37'	System	16 Sep 2020 17:37:39
	System	16 Sep 2020 17:37:39

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Sep 2020 17:49:12
User entered 'Day 8'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9fa5561b-619e-41bb-a9d3-32ac9e76a2ff' User entered 'No (N)'	System	16 Sep 2020 17:37:50
	System	16 Sep 2020 17:37:50

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-16T13:37:46', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9fa5561b-619e-41bb-a9d3-32ac9e76a2ff' User entered '16 Sep 2020 13:37'	System	16 Sep 2020 17:37:50
	System	16 Sep 2020 17:37:50

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:49:12

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Sep 2020 17:43:01
User entered 'Day 9'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0b68669f-6194-4cac-812d-64ca8b254912' User entered 'No (N)'	System	17 Sep 2020 16:57:35
	System	17 Sep 2020 16:57:35

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-17T12:57:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0b68669f-6194-4cac-812d-64ca8b254912' User entered '17 Sep 2020 12:57'	System	17 Sep 2020 16:57:35
	System	17 Sep 2020 16:57:35

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 17:43:01

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	16 Sep 2020 17:36:43
User entered 'Day 10'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:01:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '860f4325-532e-4a17-a523-312a040638f3' User entered 'No (N)'	System	18 Sep 2020 16:01:49
	System	18 Sep 2020 16:01:49

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-09-18T12:01:07', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '860f4325-532e-4a17-a523-312a040638f3' User entered '18 Sep 2020 12:01'	System	18 Sep 2020 16:01:49
	System	18 Sep 2020 16:01:49

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:36:43

US3742301

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:36:43

US3742301

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 15:17:39

US3742301

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 15:18:24
User entered '17 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 15:17:39

US3742301

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 15:17:39

US3742301

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 15:17:39

US3742301

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 15:17:44

US3742301

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	17 Sep 2020 15:17:44

US3742301

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 17:48:10

US3742301

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered '23 Sep 2020'	Sherry McCammon (b) (4)	23 Sep 2020 17:48:10

US3742301

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Sep 2020 17:48:10

US3742301

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered empty.	Sherry McCammon (b) (4)	23 Sep 2020 17:48:10

US3742301

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 17:49:03

US3742301

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	23 Sep 2020 17:49:03

US3742301

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:58:46

US3742301

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:58:46

US3742301

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:58:46

US3742301

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:58:46

US3742301

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:58:53

US3742301

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	30 Sep 2020 14:58:53

US3742301

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:22:36

US3742301

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:22:36

US3742301

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:22:36

US3742301

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'VISIT2'	System	08 Oct 2020 20:22:36

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '15:20'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '08 Oct 2020 15:20'	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '70'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'bpm'	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'breaths/min'	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '97'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '71'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 21:14:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 21:14:34
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 20:24:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16:43' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '08 Oct 2020 16:43'	System	08 Oct 2020 21:14:34
User entered empty.	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '97.6' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '64' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'bpm'	System	08 Oct 2020 21:14:34
User entered empty.	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '12' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'breaths/min'	System	08 Oct 2020 21:14:34
User entered empty.	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '110' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	08 Oct 2020 21:14:34
User entered empty.	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:14:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'mmHg'	System	08 Oct 2020 21:14:34
User entered empty.	System	08 Oct 2020 20:24:34

US3742301

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:44

US3742301

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:24:44

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Kaitlin Mason (b) (4)	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered empty.	System	04 Dec 2020 17:23:32

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16:13'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '08 Oct 2020 16:13'	System	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'ONCE'	System	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 20:26:27

US3742301

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:59

US3742301

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:59

US3742301

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '15:50'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:26:59

US3742301

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '08 Oct 2020 15:50'	System	08 Oct 2020 20:26:59

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '15:54'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered '08 Oct 2020 15:54'	System	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered empty.	System	08 Oct 2020 20:27:54

US3742301

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:28:00

US3742301

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	08 Oct 2020 20:28:00

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:11:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2920cedd-156a-4e68-b972-e2690a3c621c' User entered 'Yes (Y)'	System	08 Oct 2020 21:12:22
	System	08 Oct 2020 21:12:22

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2920cedd-156a-4e68-b972-e2690a3c621c' User entered '97.6'	System	08 Oct 2020 21:12:22
	System	08 Oct 2020 21:12:22

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2920cedd-156a-4e68-b972-e2690a3c621c' User entered 'No (N)'	System	08 Oct 2020 21:12:22
	System	08 Oct 2020 21:12:22

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2920cedd-156a-4e68-b972-e2690a3c621c' User entered '08 Oct 2020 17:12'	System	08 Oct 2020 21:12:22
	System	08 Oct 2020 21:12:22

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 16:33'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:03'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:58'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 2'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4aecf386-eff0-4e75-b893-b4c1530587b0' User entered 'Yes (Y)'	System	09 Oct 2020 16:40:37
	System	09 Oct 2020 16:40:37

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4aecf386-eff0-4e75-b893-b4c1530587b0' User entered '97.3'	System	09 Oct 2020 16:40:37
	System	09 Oct 2020 16:40:37

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:31', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4aecf386-eff0-4e75-b893-b4c1530587b0'	System	09 Oct 2020 16:40:37
User entered 'No (N)'	System	09 Oct 2020 16:40:37

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4aecf386-eff0-4e75-b893-b4c1530587b0' User entered '09 Oct 2020 12:40'	System	09 Oct 2020 16:40:37
	System	09 Oct 2020 16:40:37

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 3'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:17:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c25b4009-7237-4671-b0f4-642615e69086' User entered 'No (N)'	System	10 Oct 2020 16:17:54
	System	10 Oct 2020 16:17:54

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:17:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c25b4009-7237-4671-b0f4-642615e69086'	System	10 Oct 2020 16:17:54
User entered 'No (N)'	System	10 Oct 2020 16:17:54

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:17:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c25b4009-7237-4671-b0f4-642615e69086' User entered '10 Oct 2020 12:17'	System	10 Oct 2020 16:17:54
	System	10 Oct 2020 16:17:54

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 4'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '05316f37-5f9a-4d1d-9787-de6fdb701b1c' User entered 'Yes (Y)'	System	11 Oct 2020 17:18:36
	System	11 Oct 2020 17:18:36

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '05316f37-5f9a-4d1d-9787-de6fdb701b1c' User entered '97.2'	System	11 Oct 2020 17:18:36
	System	11 Oct 2020 17:18:36

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '05316f37-5f9a-4d1d-9787-de6fdb701b1c' User entered 'No (N)'	System	11 Oct 2020 17:18:36
	System	11 Oct 2020 17:18:36

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '05316f37-5f9a-4d1d-9787-de6fdb701b1c' User entered '11 Oct 2020 13:18'	System	11 Oct 2020 17:18:36
	System	11 Oct 2020 17:18:36

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 5'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:30:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17509ad0-a2a9-491b-9a0d-c54dee2e91d5' User entered 'Yes (Y)'	System	12 Oct 2020 16:31:03
	System	12 Oct 2020 16:31:03

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:30:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17509ad0-a2a9-491b-9a0d-c54dee2e91d5' User entered '97.2'	System	12 Oct 2020 16:31:03
	System	12 Oct 2020 16:31:03

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:30:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17509ad0-a2a9-491b-9a0d-c54dee2e91d5'	System	12 Oct 2020 16:31:03
User entered 'No (N)'	System	12 Oct 2020 16:31:03

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:30:57', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17509ad0-a2a9-491b-9a0d-c54dee2e91d5' User entered '12 Oct 2020 12:30'	System	12 Oct 2020 16:31:03
	System	12 Oct 2020 16:31:03

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 6'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:06:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f7b3f75e-07c1-4522-92fb-182e4f14b7f4' User entered 'No (N)'	System	13 Oct 2020 21:06:55
	System	13 Oct 2020 21:06:55

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:06:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f7b3f75e-07c1-4522-92fb-182e4f14b7f4' User entered 'No (N)'	System	13 Oct 2020 21:06:55
	System	13 Oct 2020 21:06:55

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:06:51', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f7b3f75e-07c1-4522-92fb-182e4f14b7f4' User entered '13 Oct 2020 17:06'	System	13 Oct 2020 21:06:55
	System	13 Oct 2020 21:06:55

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 7'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:28:41', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0ffcaff5-2c2f-4570-83b2-c84074239f21' User entered 'Yes (Y)'	System	14 Oct 2020 16:29:00
	System	14 Oct 2020 16:29:00

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:28:51', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0ffcaff5-2c2f-4570-83b2-c84074239f21' User entered '97.1'	System	14 Oct 2020 16:29:00
	System	14 Oct 2020 16:29:00

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:28:55', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0ffcaff5-2c2f-4570-83b2-c84074239f21' User entered 'No (N)'	System	14 Oct 2020 16:29:00
	System	14 Oct 2020 16:29:00

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:28:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '0ffcaff5-2c2f-4570-83b2-c84074239f21' User entered '14 Oct 2020 12:28'	System	14 Oct 2020 16:29:00
	System	14 Oct 2020 16:29:00

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2b041b3b-29a5-4758-aa95-c90236c9ce83' User entered 'None (1)'	System	08 Oct 2020 21:13:11
	System	08 Oct 2020 21:13:11

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:53', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2b041b3b-29a5-4758-aa95-c90236c9ce83' User entered 'No (N)'	System	08 Oct 2020 21:13:11
	System	08 Oct 2020 21:13:11

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2b041b3b-29a5-4758-aa95-c90236c9ce83' User entered 'No (N)'	System	08 Oct 2020 21:13:11
	System	08 Oct 2020 21:13:11

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:13:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2b041b3b-29a5-4758-aa95-c90236c9ce83' User entered 'None (1)'	System	08 Oct 2020 21:13:11
	System	08 Oct 2020 21:13:11

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:13:07', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2b041b3b-29a5-4758-aa95-c90236c9ce83' User entered '08 Oct 2020 17:13'	System	08 Oct 2020 21:13:11
	System	08 Oct 2020 21:13:11

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 16:33'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:03'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:58'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 2'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:20', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fa6e93a7-d79f-41f9-958b-f4fd2d9de4a9'	System	09 Oct 2020 16:41:40
User entered 'None (1)'	System	09 Oct 2020 16:41:40

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fa6e93a7-d79f-41f9-958b-f4fd2d9de4a9'	System	09 Oct 2020 16:41:40
User entered 'No (N)'	System	09 Oct 2020 16:41:40

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fa6e93a7-d79f-41f9-958b-f4fd2d9de4a9'	System	09 Oct 2020 16:41:40
User entered 'No (N)'	System	09 Oct 2020 16:41:40

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fa6e93a7-d79f-41f9-958b-f4fd2d9de4a9'	System	09 Oct 2020 16:41:40
User entered 'None (1)'	System	09 Oct 2020 16:41:40

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fa6e93a7-d79f-41f9-958b-f4fd2d9de4a9' User entered '09 Oct 2020 12:41'	System	09 Oct 2020 16:41:40
	System	09 Oct 2020 16:41:40

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 3'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '02cb5e56-8bbc-4bd3-9dce-675f90d3b839' User entered 'None (1)'	System	10 Oct 2020 16:18:50
	System	10 Oct 2020 16:18:50

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:38', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '02cb5e56-8bbc-4bd3-9dce-675f90d3b839'	System	10 Oct 2020 16:18:50
User entered 'No (N)'	System	10 Oct 2020 16:18:50

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '02cb5e56-8bbc-4bd3-9dce-675f90d3b839' User entered 'No (N)'	System	10 Oct 2020 16:18:50
	System	10 Oct 2020 16:18:50

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '02cb5e56-8bbc-4bd3-9dce-675f90d3b839' User entered 'None (1)'	System	10 Oct 2020 16:18:50
	System	10 Oct 2020 16:18:50

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '02cb5e56-8bbc-4bd3-9dce-675f90d3b839' User entered '10 Oct 2020 12:18'	System	10 Oct 2020 16:18:50
	System	10 Oct 2020 16:18:50

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 4'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:19', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd6b35a21-47c6-4ac7-9566-c597f4744afd' User entered 'None (1)'	System	11 Oct 2020 17:19:35
	System	11 Oct 2020 17:19:35

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:22', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd6b35a21-47c6-4ac7-9566-c597f4744afd' User entered 'No (N)'	System	11 Oct 2020 17:19:35
	System	11 Oct 2020 17:19:35

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd6b35a21-47c6-4ac7-9566-c597f4744afd' User entered 'No (N)'	System	11 Oct 2020 17:19:35
	System	11 Oct 2020 17:19:35

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:30', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd6b35a21-47c6-4ac7-9566-c597f4744afd' User entered 'None (1)'	System	11 Oct 2020 17:19:35
	System	11 Oct 2020 17:19:35

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd6b35a21-47c6-4ac7-9566-c597f4744afd' User entered '11 Oct 2020 13:19'	System	11 Oct 2020 17:19:35
	System	11 Oct 2020 17:19:35

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 5'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5891ab50-eaf6-414c-bb45-f6efcb875b3d'	System	12 Oct 2020 16:32:37
User entered 'None (1)'	System	12 Oct 2020 16:32:37

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5891ab50-eaf6-414c-bb45-f6efcb875b3d' User entered 'No (N)'	System	12 Oct 2020 16:32:37
	System	12 Oct 2020 16:32:37

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:38', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5891ab50-eaf6-414c-bb45-f6efcb875b3d' User entered 'No (N)'	System	12 Oct 2020 16:32:37
	System	12 Oct 2020 16:32:37

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5891ab50-eaf6-414c-bb45-f6efcb875b3d' User entered 'None (1)'	System	12 Oct 2020 16:32:37
	System	12 Oct 2020 16:32:37

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:45', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5891ab50-eaf6-414c-bb45-f6efcb875b3d' User entered '12 Oct 2020 12:31'	System	12 Oct 2020 16:32:37
	System	12 Oct 2020 16:32:37

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 6'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:06:57', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '62265bd7-e965-43d3-bafd-3d33b91cfd70' User entered 'None (1)'	System	13 Oct 2020 21:07:14
	System	13 Oct 2020 21:07:14

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '62265bd7-e965-43d3-bafd-3d33b91cfd70' User entered 'No (N)'	System	13 Oct 2020 21:07:14
	System	13 Oct 2020 21:07:14

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '62265bd7-e965-43d3-bafd-3d33b91cfd70' User entered 'No (N)'	System	13 Oct 2020 21:07:14
	System	13 Oct 2020 21:07:14

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:07', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '62265bd7-e965-43d3-bafd-3d33b91cfd70' User entered 'None (1)'	System	13 Oct 2020 21:07:14
	System	13 Oct 2020 21:07:14

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:10', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '62265bd7-e965-43d3-bafd-3d33b91cfd70' User entered '13 Oct 2020 17:07'	System	13 Oct 2020 21:07:14
	System	13 Oct 2020 21:07:14

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 7'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a76851b9-505f-4a14-b7cb-c98354260b65' User entered 'None (1)'	System	14 Oct 2020 16:29:23
	System	14 Oct 2020 16:29:23

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a76851b9-505f-4a14-b7cb-c98354260b65' User entered 'No (N)'	System	14 Oct 2020 16:29:23
	System	14 Oct 2020 16:29:23

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a76851b9-505f-4a14-b7cb-c98354260b65'	System	14 Oct 2020 16:29:23
User entered 'No (N)'	System	14 Oct 2020 16:29:23

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a76851b9-505f-4a14-b7cb-c98354260b65' User entered 'None (1)'	System	14 Oct 2020 16:29:23
	System	14 Oct 2020 16:29:23

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:18', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a76851b9-505f-4a14-b7cb-c98354260b65' User entered '14 Oct 2020 12:29'	System	14 Oct 2020 16:29:23
	System	14 Oct 2020 16:29:23

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:26', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:28', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'None (0)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered 'No (N)'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-08T17:12:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '37b3c13d-8fc5-41f4-8be6-34c584d41c6d' User entered '08 Oct 2020 17:12'	System	08 Oct 2020 21:12:47
	System	08 Oct 2020 21:12:47

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 16:33'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:03'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '08 Oct 2020 19:58'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 2'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:42', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3'	System	09 Oct 2020 16:41:15
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3'	System	09 Oct 2020 16:41:15
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3' User entered 'None (0)'	System	09 Oct 2020 16:41:15
	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:40:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3' User entered 'None (0)'	System	09 Oct 2020 16:41:15
	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:02', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3' User entered 'None (0)'	System	09 Oct 2020 16:41:15
	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:06', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3'	System	09 Oct 2020 16:41:15
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3' User entered 'No (N)'	System	09 Oct 2020 16:41:15
	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-09T12:41:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c8489233-e883-45a8-9177-97eb03dd23e3' User entered '09 Oct 2020 12:41'	System	09 Oct 2020 16:41:15
	System	09 Oct 2020 16:41:15

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 3'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:17:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57' User entered 'None (0)'	System	10 Oct 2020 16:18:31
	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:04', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57'	System	10 Oct 2020 16:18:31
User entered 'No interference with activity (1)'	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57'	System	10 Oct 2020 16:18:31
User entered 'No interference with activity (1)'	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57' User entered 'None (0)'	System	10 Oct 2020 16:18:31
	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57' User entered 'None (0)'	System	10 Oct 2020 16:18:31
	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:20', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57'	System	10 Oct 2020 16:18:31
User entered 'No interference with activity (1)'	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57' User entered 'No (N)'	System	10 Oct 2020 16:18:31
	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-10T12:18:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'ec4aac7d-2504-4425-938c-d68f182d2f57' User entered '10 Oct 2020 12:18'	System	10 Oct 2020 16:18:31
	System	10 Oct 2020 16:18:31

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 4'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:42', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d'	System	11 Oct 2020 17:19:13
User entered 'No interference with activity (1)'	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d'	System	11 Oct 2020 17:19:13
User entered 'No interference with activity (1)'	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d' User entered 'None (0)'	System	11 Oct 2020 17:19:13
	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:55', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d' User entered 'None (0)'	System	11 Oct 2020 17:19:13
	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:18:58', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d' User entered 'None (0)'	System	11 Oct 2020 17:19:13
	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:02', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d'	System	11 Oct 2020 17:19:13
User entered 'No interference with activity (1)'	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:06', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d' User entered 'No (N)'	System	11 Oct 2020 17:19:13
	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-11T13:19:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2035c618-d068-49c2-b6aa-5faf4f85c97d' User entered '11 Oct 2020 13:19'	System	11 Oct 2020 17:19:13
	System	11 Oct 2020 17:19:13

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 5'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered 'No interference with activity (1)'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d'	System	12 Oct 2020 16:31:33
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:12', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered 'None (0)'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered 'None (0)'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered 'None (0)'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:20', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d'	System	12 Oct 2020 16:31:33
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:25', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered 'No (N)'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-12T12:31:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1047f8c4-1baa-41c6-8c53-54081582002d' User entered '12 Oct 2020 12:31'	System	12 Oct 2020 16:31:33
	System	12 Oct 2020 16:31:33

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 6'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered 'None (0)'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6'	System	13 Oct 2020 21:07:46
User entered 'No interference with activity (1)'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered 'None (0)'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:30', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered 'None (0)'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered 'None (0)'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:36', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6'	System	13 Oct 2020 21:07:46
User entered 'No interference with activity (1)'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:42', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered 'No (N)'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-13T17:07:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd787b68b-6039-4dff-b10c-71b6256714c6' User entered '13 Oct 2020 17:07'	System	13 Oct 2020 21:07:46
	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	08 Oct 2020 20:26:27
User entered 'Day 7'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:24', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered 'None (0)'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered 'None (0)'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d'	System	14 Oct 2020 16:29:54
User entered 'No interference with activity (1)'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered 'No interference with activity (1)'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered 'None (0)'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d'	System	14 Oct 2020 16:29:54
User entered 'No interference with activity (1)'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered 'No (N)'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-14T12:29:50', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '094e6f57-8b89-49b1-bb08-0d3896dc831d' User entered '14 Oct 2020 12:29'	System	14 Oct 2020 16:29:54
	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:26:27

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 8'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd8a7cbcc-fc95-4704-bb26-873c4d424b75'	System	15 Oct 2020 17:30:08
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd8a7cbcc-fc95-4704-bb26-873c4d424b75' User entered '15 Oct 2020 13:30'	System	15 Oct 2020 17:30:08
	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 9'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:14', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c1151346-d596-4c97-b673-d4eca2005271'	System	16 Oct 2020 16:04:20
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:04:20

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'c1151346-d596-4c97-b673-d4eca2005271' User entered '16 Oct 2020 12:04'	System	16 Oct 2020 16:04:20
	System	16 Oct 2020 16:04:20

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Oct 2020 17:30:08
User entered 'Day 10'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f21ac0b7-088a-4898-b9eb-8be02ecd9b5c' User entered 'None (0)'	System	17 Oct 2020 19:47:14
	System	17 Oct 2020 19:47:14

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:12', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'f21ac0b7-088a-4898-b9eb-8be02ecd9b5c' User entered '17 Oct 2020 15:47'	System	17 Oct 2020 19:47:14
	System	17 Oct 2020 19:47:14

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 8'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ad2e46a-fcb8-4f66-85c7-273347a442af' User entered 'No interference with activity (1)'	System	15 Oct 2020 17:30:24
	System	15 Oct 2020 17:30:24

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:18', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '1ad2e46a-fcb8-4f66-85c7-273347a442af' User entered '15 Oct 2020 13:30'	System	15 Oct 2020 17:30:24
	System	15 Oct 2020 17:30:24

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 9'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:26', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4bc8e65-9f34-4f5e-983f-d6b324c4cdb3'	System	16 Oct 2020 16:04:36
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:04:36

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:31', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a4bc8e65-9f34-4f5e-983f-d6b324c4cdb3' User entered '16 Oct 2020 12:04'	System	16 Oct 2020 16:04:36
	System	16 Oct 2020 16:04:36

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Oct 2020 17:30:24
User entered 'Day 10'	System	15 Oct 2020 17:30:24

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:18', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a45ef566-66f6-41e7-a4a0-3aedccab98c9'	System	17 Oct 2020 19:47:22
User entered 'No interference with activity (1)'	System	17 Oct 2020 19:47:22

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:21', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a45ef566-66f6-41e7-a4a0-3aedccab98c9' User entered '17 Oct 2020 15:47'	System	17 Oct 2020 19:47:22
	System	17 Oct 2020 19:47:22

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:30:24

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:30:24

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	16 Oct 2020 16:04:36
User entered 'Day 11'	System	16 Oct 2020 16:04:36

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-18T12:50:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'caf86c5f-31a3-494f-a692-5b9acf9a7ce5' User entered 'None (0)'	System	18 Oct 2020 16:50:56
	System	18 Oct 2020 16:50:56

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-18T12:50:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'caf86c5f-31a3-494f-a692-5b9acf9a7ce5' User entered '18 Oct 2020 12:50'	System	18 Oct 2020 16:50:56
	System	18 Oct 2020 16:50:56

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:04:36

US3742301

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:04:36

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	13 Oct 2020 21:07:46
User entered 'Day 8'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '324447d2-9835-459a-84ff-8b246be25443'	System	15 Oct 2020 17:30:30
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:30:30

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:27', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '324447d2-9835-459a-84ff-8b246be25443' User entered '15 Oct 2020 13:30'	System	15 Oct 2020 17:30:30
	System	15 Oct 2020 17:30:30

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 9'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fc019d3a-4731-4e7d-81f8-b4645a948bb0'	System	16 Oct 2020 16:04:39
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:04:39

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'fc019d3a-4731-4e7d-81f8-b4645a948bb0' User entered '16 Oct 2020 12:04'	System	16 Oct 2020 16:04:39
	System	16 Oct 2020 16:04:39

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Oct 2020 17:30:30
User entered 'Day 10'	System	15 Oct 2020 17:30:30

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:28', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'aaff4bc5-fa7e-4d52-a558-5cb21ac58146' User entered 'None (0)'	System	17 Oct 2020 19:47:36
	System	17 Oct 2020 19:47:36

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:30:30

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:30:30

US3742301

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:31', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'aaff4bc5-fa7e-4d52-a558-5cb21ac58146' User entered '17 Oct 2020 15:47'	System	17 Oct 2020 19:47:36
	System	17 Oct 2020 19:47:36

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	13 Oct 2020 21:07:46
User entered 'Day 8'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '57ae9ebb-b40f-4a20-8a41-96c4b7f2fd7e' User entered 'No (N)'	System	15 Oct 2020 17:30:42
	System	15 Oct 2020 17:30:42

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-15T13:30:36', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '57ae9ebb-b40f-4a20-8a41-96c4b7f2fd7e' User entered '15 Oct 2020 13:30'	System	15 Oct 2020 17:30:42
	System	15 Oct 2020 17:30:42

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 21:07:46

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	14 Oct 2020 16:29:54
User entered 'Day 9'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3eec760a-22c0-4637-894e-5f04d271c9bd' User entered 'No (N)'	System	16 Oct 2020 16:04:50
	System	16 Oct 2020 16:04:50

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-16T12:04:48', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3eec760a-22c0-4637-894e-5f04d271c9bd' User entered '16 Oct 2020 12:04'	System	16 Oct 2020 16:04:50
	System	16 Oct 2020 16:04:50

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:29:54

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	15 Oct 2020 17:30:08
User entered 'Day 10'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:35', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17e9050c-eeb9-4f33-8268-fe00f67762b3' User entered 'No (N)'	System	17 Oct 2020 19:47:42
	System	17 Oct 2020 19:47:42

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-10-17T15:47:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '17e9050c-eeb9-4f33-8268-fe00f67762b3' User entered '17 Oct 2020 15:47'	System	17 Oct 2020 19:47:42
	System	17 Oct 2020 19:47:42

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:30:08

US3742301

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:31:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:30:08

US3742301

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 13:53:05

US3742301

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered '16 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 13:53:05

US3742301

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	20 Oct 2020 13:53:05

US3742301

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 13:53:05
	(b) (4)	

US3742301

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 13:53:11

US3742301

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	20 Oct 2020 13:53:11

US3742301

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:01:31

US3742301

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 20:01:31

US3742301

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	23 Oct 2020 20:01:31

US3742301

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:01:31

US3742301

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:01:37

US3742301

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	23 Oct 2020 20:01:37

US3742301

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Oct 2020 12:25:23

US3742301

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '31 Oct 2020'	Hassan Haji (b) (4)	31 Oct 2020 12:25:23

US3742301

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	31 Oct 2020 12:25:23

US3742301

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:25:23

US3742301

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:40:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Oct 2020 12:25:28

US3742301

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	31 Oct 2020 12:25:28

US3742301

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Nov 2020 14:47:36

US3742301

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '05 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	06 Nov 2020 14:47:36

US3742301

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	06 Nov 2020 14:47:36

US3742301

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered 'VISIT3'	System	06 Nov 2020 14:47:36

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'No (N)'	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered empty.	System	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered empty.	System	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered empty.	System	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered empty.	System	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered empty.	Sherry McCammon (b) (4)	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered empty.	System	06 Nov 2020 14:47:42

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29

US3742301

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29

US3742301

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:41

US3742301

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '05 Nov 2020'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:41

US3742301

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:09

US3742301

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '05 Nov 2020'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:09

US3742301

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered '16:42'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:09

US3742301

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered '05 Nov 2020 16:42'	System	06 Nov 2020 14:48:09

US3742301

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:41:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Nov 2020 14:48:15

US3742301

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:29
User entered 'I'	System	06 Nov 2020 14:48:15

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 64'	System	09 Sep 2020 20:29:56

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-09T11:58:44', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cccf78c-0a4a-4e59-8d5a-330b1463be53'	System	09 Nov 2020 16:59:11
User entered 'No (N)'	System	09 Nov 2020 16:59:11

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-09T11:58:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cccf78c-0a4a-4e59-8d5a-330b1463be53'	System	09 Nov 2020 16:59:11
User entered 'No (N)'	System	09 Nov 2020 16:59:11

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-09T11:59:02', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cccf78c-0a4a-4e59-8d5a-330b1463be53' User entered '09 Nov 2020 11:59:02'	System	09 Nov 2020 16:59:11
	System	09 Nov 2020 16:59:11

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 20:29:56

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered 'Day 71'	System	09 Sep 2020 20:29:56

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-16T14:48:19', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4258cbb8-3ad9-4c8d-9b7b-7e82cf4974e9' User entered 'No (N)'	System	16 Nov 2020 19:48:34
	System	16 Nov 2020 19:48:34

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-16T14:48:25', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4258cbb8-3ad9-4c8d-9b7b-7e82cf4974e9'	System	16 Nov 2020 19:48:34
User entered 'No (N)'	System	16 Nov 2020 19:48:34

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-16T14:48:30', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '4258cbb8-3ad9-4c8d-9b7b-7e82cf4974e9' User entered '16 Nov 2020 14:48:30'	System	16 Nov 2020 19:48:34
	System	16 Nov 2020 19:48:34

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 20:29:56

US3742301

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:32:16
Data entry locked.	System	09 Sep 2020 20:29:56
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 20:29:56

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-20T12:33:03', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'b9f709c5-e317-4da8-9a32-a5e33d899a01'	System	20 Nov 2020 17:33:16
User entered 'No (N)'	System	20 Nov 2020 17:33:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-20T12:33:09', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'b9f709c5-e317-4da8-9a32-a5e33d899a01'	System	20 Nov 2020 17:33:16
User entered 'No (N)'	System	20 Nov 2020 17:33:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-20T12:33:13', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'b9f709c5-e317-4da8-9a32-a5e33d899a01' User entered '20 Nov 2020 12:33:13'	System	20 Nov 2020 17:33:16
	System	20 Nov 2020 17:33:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-27T10:40:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5e952153-e53a-4f35-94bd-21105dadcb5' User entered 'No (N)'	System	27 Nov 2020 15:41:04
	System	27 Nov 2020 15:41:04

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-27T10:40:57', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5e952153-e53a-4f35-94bd-21105dadcb5' User entered 'No (N)'	System	27 Nov 2020 15:41:04

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-11-27T10:41:01', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5e952153-e53a-4f35-94bd-21105dadccb5' User entered '27 Nov 2020 10:41:01'	System	27 Nov 2020 15:41:04
	System	27 Nov 2020 15:41:04

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-04T00:02:06', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5ce283c2-cf8a-4fdc-862a-3715ce3312b1' User entered 'No (N)'	System	04 Dec 2020 05:02:29
	System	04 Dec 2020 05:02:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-04T00:02:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5ce283c2-cf8a-4fdc-862a-3715ce3312b1' User entered 'No (N)'	System	04 Dec 2020 05:02:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-04T00:02:15', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '5ce283c2-cf8a-4fdc-862a-3715ce3312b1' User entered '04 Dec 2020 00:02:15'	System	04 Dec 2020 05:02:29
	System	04 Dec 2020 05:02:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-11T11:39:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98c88341-7734-46bf-9958-f852e0078ebe' User entered 'No (N)'	System	11 Dec 2020 16:39:43
	System	11 Dec 2020 16:39:43

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-11T11:39:36', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98c88341-7734-46bf-9958-f852e0078ebe' User entered 'No (N)'	System	11 Dec 2020 16:39:43
	System	11 Dec 2020 16:39:43

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-11T11:39:39', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98c88341-7734-46bf-9958-f852e0078ebe' User entered '11 Dec 2020 11:39:39'	System	11 Dec 2020 16:39:43
	System	11 Dec 2020 16:39:43

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-18T14:40:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '08fea511-d6a1-49b9-ae3c-430323e98721' User entered 'No (N)'	System	18 Dec 2020 19:40:51
	System	18 Dec 2020 19:40:51

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-18T14:40:43', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '08fea511-d6a1-49b9-ae3c-430323e98721' User entered 'No (N)'	System	18 Dec 2020 19:40:51

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-18T14:40:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '08fea511-d6a1-49b9-ae3c-430323e98721' User entered '18 Dec 2020 14:40:47'	System	18 Dec 2020 19:40:51
	System	18 Dec 2020 19:40:51

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-25T10:51:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9ffce0b1-86b1-49c4-bfca-4dea524ae353'	System	25 Dec 2020 15:52:14
User entered 'No (N)'	System	25 Dec 2020 15:52:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-25T10:52:04', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9ffce0b1-86b1-49c4-bfca-4dea524ae353'	System	25 Dec 2020 15:52:14
User entered 'No (N)'	System	25 Dec 2020 15:52:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2020-12-25T10:52:10', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '9ffce0b1-86b1-49c4-bfca-4dea524ae353' User entered '25 Dec 2020 10:52:10'	System	25 Dec 2020 15:52:14
	System	25 Dec 2020 15:52:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-01T13:16:04', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3016df5b-a261-4038-9e80-750b89d7b43c' User entered 'No (N)'	System	01 Jan 2021 18:16:17
	System	01 Jan 2021 18:16:17

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-01T13:16:10', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3016df5b-a261-4038-9e80-750b89d7b43c' User entered 'No (N)'	System	01 Jan 2021 18:16:17
	System	01 Jan 2021 18:16:17

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-01T13:16:16', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3016df5b-a261-4038-9e80-750b89d7b43c' User entered '01 Jan 2021 13:16:16'	System	01 Jan 2021 18:16:17
	System	01 Jan 2021 18:16:17

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-08T11:13:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '00bb6b14-7ea5-43fd-b300-581095681ca9' User entered 'No (N)'	System	08 Jan 2021 16:13:39
	System	08 Jan 2021 16:13:39

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-08T11:13:32', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '00bb6b14-7ea5-43fd-b300-581095681ca9'	System	08 Jan 2021 16:13:39
User entered 'No (N)'	System	08 Jan 2021 16:13:39

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-08T11:13:36', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '00bb6b14-7ea5-43fd-b300-581095681ca9' User entered '08 Jan 2021 11:13:36'	System	08 Jan 2021 16:13:39
	System	08 Jan 2021 16:13:39

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-15T07:54:47', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd08b6609-747e-42fd-b092-3169c9879676' User entered 'No (N)'	System	15 Jan 2021 12:55:00
	System	15 Jan 2021 12:55:00

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-15T07:54:52', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd08b6609-747e-42fd-b092-3169c9879676'	System	15 Jan 2021 12:55:00
User entered 'No (N)'	System	15 Jan 2021 12:55:00

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-15T07:54:57', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'd08b6609-747e-42fd-b092-3169c9879676' User entered '15 Jan 2021 07:54:57'	System	15 Jan 2021 12:55:00

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-22T11:22:29', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a840ca94-a162-4d4a-be15-e7b4886f734b' User entered 'No (N)'	System	22 Jan 2021 16:22:41

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-22T11:22:34', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a840ca94-a162-4d4a-be15-e7b4886f734b' User entered 'No (N)'	System	22 Jan 2021 16:22:41

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-22T11:22:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a840ca94-a162-4d4a-be15-e7b4886f734b' User entered '22 Jan 2021 11:22:37'	System	22 Jan 2021 16:22:41
	System	22 Jan 2021 16:22:41

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-29T12:35:59', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'abe904bf-bac2-409a-b44a-ad5adb49d21c' User entered 'No (N)'	System	29 Jan 2021 17:36:14
	System	29 Jan 2021 17:36:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-29T12:36:05', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'abe904bf-bac2-409a-b44a-ad5adb49d21c'	System	29 Jan 2021 17:36:14
User entered 'No (N)'	System	29 Jan 2021 17:36:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-01-29T12:36:08', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'abe904bf-bac2-409a-b44a-ad5adb49d21c' User entered '29 Jan 2021 12:36:08'	System	29 Jan 2021 17:36:14
	System	29 Jan 2021 17:36:14

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-06T12:20:33', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a1ca6e98-40d3-4f0f-b746-b8e4db89ceac'	System	06 Feb 2021 17:20:42
User entered 'No (N)'	System	06 Feb 2021 17:20:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-06T12:20:37', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a1ca6e98-40d3-4f0f-b746-b8e4db89ceac'	System	06 Feb 2021 17:20:42
User entered 'No (N)'	System	06 Feb 2021 17:20:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-06T12:20:40', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'a1ca6e98-40d3-4f0f-b746-b8e4db89ceac' User entered '06 Feb 2021 12:20:40'	System	06 Feb 2021 17:20:42
	System	06 Feb 2021 17:20:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-12T16:21:49', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6ce483a2-5f6e-480b-9722-291529d6f8a9'	System	12 Feb 2021 23:49:16
User entered 'No (N)'	System	12 Feb 2021 23:49:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-12T16:21:53', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6ce483a2-5f6e-480b-9722-291529d6f8a9'	System	12 Feb 2021 23:49:16
User entered 'No (N)'	System	12 Feb 2021 23:49:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-12T16:21:56', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6ce483a2-5f6e-480b-9722-291529d6f8a9' User entered '12 Feb 2021 16:21:56'	System	12 Feb 2021 23:49:16
	System	12 Feb 2021 23:49:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-19T14:20:11', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e593367a-d406-490b-8f1d-41d6f8a8cd3a' User entered 'No (N)'	System	19 Feb 2021 19:20:26
	System	19 Feb 2021 19:20:26

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-19T14:20:17', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e593367a-d406-490b-8f1d-41d6f8a8cd3a' User entered 'No (N)'	System	19 Feb 2021 19:20:26
	System	19 Feb 2021 19:20:26

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-19T14:20:23', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e593367a-d406-490b-8f1d-41d6f8a8cd3a' User entered '19 Feb 2021 14:20:23'	System	19 Feb 2021 19:20:26
	System	19 Feb 2021 19:20:26

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-26T12:14:54-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '22a28ec9-d48c-4630-a9b1-0e93210fcd79' User entered 'No (N)'	System	26 Feb 2021 17:21:46
	System	26 Feb 2021 17:21:46

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-26T12:14:59-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '22a28ec9-d48c-4630-a9b1-0e93210fcd79' User entered 'No (N)'	System	26 Feb 2021 17:21:46
	System	26 Feb 2021 17:21:46

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-02-26T12:15:02-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '22a28ec9-d48c-4630-a9b1-0e93210fcd79' User entered '26 Feb 2021 17:15:02'	System	26 Feb 2021 17:21:46
	System	26 Feb 2021 17:21:46

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-05T12:01:02-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6e67136d-ea58-448e-aede-b83893c913dd'	System	05 Mar 2021 17:04:29
User entered 'No (N)'	System	05 Mar 2021 17:04:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-05T12:01:06-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6e67136d-ea58-448e-aede-b83893c913dd'	System	05 Mar 2021 17:04:29
User entered 'No (N)'	System	05 Mar 2021 17:04:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-05T12:01:10-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6e67136d-ea58-448e-aede-b83893c913dd' User entered '05 Mar 2021 12:01:10'	System	05 Mar 2021 17:04:29
	System	05 Mar 2021 17:04:29

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-12T12:24:48-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3e2314bf-dcc1-4e30-bd55-5dcd01e8121b' User entered 'No (N)'	System	12 Mar 2021 17:24:59
	System	12 Mar 2021 17:24:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-12T12:24:52-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3e2314bf-dcc1-4e30-bd55-5dcd01e8121b' User entered 'No (N)'	System	12 Mar 2021 17:24:59
	System	12 Mar 2021 17:24:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-12T12:24:55-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '3e2314bf-dcc1-4e30-bd55-5dcd01e8121b' User entered '12 Mar 2021 12:24:55'	System	12 Mar 2021 17:24:59
	System	12 Mar 2021 17:24:59

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-19T17:09:30-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '95c96cbe-fe90-430f-9897-ad204266a422'	System	19 Mar 2021 21:09:42
User entered 'No (N)'	System	19 Mar 2021 21:09:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-19T17:09:34-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '95c96cbe-fe90-430f-9897-ad204266a422'	System	19 Mar 2021 21:09:42
User entered 'No (N)'	System	19 Mar 2021 21:09:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-19T17:09:39-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '95c96cbe-fe90-430f-9897-ad204266a422'	System	19 Mar 2021 21:09:42
User entered '19 Mar 2021 17:09:39'	System	19 Mar 2021 21:09:42

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-26T14:57:07-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2f49e1b7-c1de-41ab-8edf-15908c2b3b36'	System	26 Mar 2021 18:57:16
User entered 'No (N)'	System	26 Mar 2021 18:57:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-26T14:57:11-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2f49e1b7-c1de-41ab-8edf-15908c2b3b36'	System	26 Mar 2021 18:57:16
User entered 'No (N)'	System	26 Mar 2021 18:57:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-26T14:57:14-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '2f49e1b7-c1de-41ab-8edf-15908c2b3b36'	System	26 Mar 2021 18:57:16
User entered '26 Mar 2021 14:57:14'	System	26 Mar 2021 18:57:16

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-02T20:32:03-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98099331-5f54-4150-87a4-84b866017704'	System	03 Apr 2021 00:32:12
User entered 'No (N)'	System	03 Apr 2021 00:32:12

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-02T20:32:07-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98099331-5f54-4150-87a4-84b866017704'	System	03 Apr 2021 00:32:12
User entered 'No (N)'	System	03 Apr 2021 00:32:12

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-02T20:32:10-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '98099331-5f54-4150-87a4-84b866017704'	System	03 Apr 2021 00:32:12
User entered '02 Apr 2021 20:32:10'	System	03 Apr 2021 00:32:12

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-09T12:44:53-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e6c89d11-6631-4dd0-916d-a81b23ed1b98'	System	09 Apr 2021 16:45:08
User entered 'No (N)'	System	09 Apr 2021 16:45:08

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-09T12:44:56-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e6c89d11-6631-4dd0-916d-a81b23ed1b98'	System	09 Apr 2021 16:45:08
User entered 'No (N)'	System	09 Apr 2021 16:45:08

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-09T12:45:00-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e6c89d11-6631-4dd0-916d-a81b23ed1b98'	System	09 Apr 2021 16:45:08
User entered '09 Apr 2021 12:45:00'	System	09 Apr 2021 16:45:08

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-16T14:17:44-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e8be35c3-feb1-4050-b614-6bbafa4a94a0'	System	16 Apr 2021 18:17:58
User entered 'No (N)'	System	16 Apr 2021 18:17:58

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-16T14:17:50-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e8be35c3-feb1-4050-b614-6bbafa4a94a0'	System	16 Apr 2021 18:17:58
User entered 'No (N)'	System	16 Apr 2021 18:17:58

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-16T14:17:53-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'e8be35c3-feb1-4050-b614-6bbafa4a94a0' User entered '16 Apr 2021 14:17:53'	System	16 Apr 2021 18:17:58
	System	16 Apr 2021 18:17:58

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-23T12:44:48-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6325c450-0433-41ae-8ae3-3103e414758b'	System	23 Apr 2021 16:44:57
User entered 'No (N)'	System	23 Apr 2021 16:44:57

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-23T12:44:51-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6325c450-0433-41ae-8ae3-3103e414758b'	System	23 Apr 2021 16:44:57
User entered 'No (N)'	System	23 Apr 2021 16:44:57

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-23T12:44:55-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '6325c450-0433-41ae-8ae3-3103e414758b'	System	23 Apr 2021 16:44:57
User entered '23 Apr 2021 12:44:55'	System	23 Apr 2021 16:44:57

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-30T15:46:44-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cab4e6d7-82dd-472e-94e6-4534f1a29816' User entered 'No (N)'	System	30 Apr 2021 19:47:30
	System	30 Apr 2021 19:47:30

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

Have you been exposed to someone with 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 (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-30T15:47:21-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cab4e6d7-82dd-472e-94e6-4534f1a29816'	System	30 Apr 2021 19:47:30
User entered 'No (N)'	System	30 Apr 2021 19:47:30

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-04-30T15:47:26-04:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: 'cab4e6d7-82dd-472e-94e6-4534f1a29816'	System	30 Apr 2021 19:47:30
User entered '30 Apr 2021 15:47:26'	System	30 Apr 2021 19:47:30

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:44:01

US3742301

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:01
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:44:01

US3742301

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:42

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 21:09:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-05T12:01:32-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '92f8a212-5e12-4f1d-92e0-abe70c144d05'	System	05 Mar 2021 17:07:41
User entered 'No (N)'	System	05 Mar 2021 17:07:41

US3742301

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824C7A4F-4687-43AB-B803-EC843D072FDD)', Time: '2021-03-05T12:01:43-05:00', User OID: 'PatientReportedOutcome (US3742301)', ODM File OID: '92f8a212-5e12-4f1d-92e0-abe70c144d05' User entered '05 Mar 2021 12:01:43'	System	05 Mar 2021 17:07:41
	System	05 Mar 2021 17:07:41

US3742301

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:45:17

US3742301

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:45:17

US3742301

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:45:17

US3742301

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:45:17

US3742301

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:45:19

US3742301

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:33:23
User entered 'I'	System	03 Dec 2020 19:45:19

US3742301

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Jan 2021 16:51:40

US3742301

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '8 Jan 2021'	Sherry McCammon (b) (4)	12 Jan 2021 16:51:40

US3742301

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	12 Jan 2021 16:51:40

US3742301

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Sherry McCammon (b) (4)	12 Jan 2021 16:51:40

US3742301

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Jan 2021 16:51:45

US3742301

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User entered 'I'	System	12 Jan 2021 16:51:45

US3742301

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 22:12:00

US3742301

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 22:12:00

US3742301

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 22:12:00

US3742301

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User closed query 'Per DM CLR: Comment = HAD AN EMERGENCY SURGERY TO CORRECT ISSUE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 08:42:27
Query 'Per DM CLR: Comment = HAD AN EMERGENCY SURGERY TO CORRECT ISSUE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 17:56:11
User opened query 'Per DM CLR: Comment = HAD AN EMERGENCY SURGERY TO CORRECT ISSUE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 10:27:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Now reports she was admitted for "twisted intestines" and had an emergency surgery to correct issue - was admitted and discharged. No changes to medication per participant.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:13:52
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 22:12:00

US3742301

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 22:11:48

US3742301

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:48:52
User entered 'I'	System	03 Feb 2021 22:11:48

US3742301

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 18:20:06

US3742301

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
	(b) (4)	
User entered '5 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 18:20:06

US3742301

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Mar 2021 18:20:06

US3742301

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:20:06

US3742301

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 18:20:13

US3742301

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:42
User entered 'I'	System	08 Mar 2021 18:20:13

US3742301

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:42

US3742301

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:42

US3742301

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:42

US3742301

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered 'VISIT4'	System	02 Apr 2021 19:35:42

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered empty.	System	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered empty.	System	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered empty.	System	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered empty.	System	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered empty.	System	02 Apr 2021 19:35:49

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51

US3742301

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51

US3742301

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:57

US3742301

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:35:57

US3742301

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:36:24

US3742301

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:36:24

US3742301

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '12:20'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:36:24

US3742301

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered '25 Mar 2021 12:20'	System	02 Apr 2021 19:36:24

US3742301

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:36:31

US3742301

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:02:51
User entered 'I'	System	02 Apr 2021 19:36:31

US3742301

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:24

US3742301

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:24

US3742301

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:24

US3742301

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 18:03:24

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:26:11
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:26:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '06 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[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 22:16:55
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:26:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:58:47

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:26:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:58:47

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:32:28
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:32:28
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '1'	System	14 Jan 2021 18:03:59

US3742301

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'I'	System	14 Jan 2021 18:03:59

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	14 Jan 2021 21:09:35
DataPoint set to visible.	System	14 Jan 2021 18:03:59

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	14 Jan 2021 21:09:35
DataPoint set to visible.	System	14 Jan 2021 18:03:59

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11:10'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '14 Jan 2021 11:10'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '99.2' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '64'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'bpm'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'breaths/min'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '130'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '85'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	14 Jan 2021 21:09:35
DataPoint set to visible.	System	14 Jan 2021 18:03:59

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '12:03'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '14 Jan 2021 12:03'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '56'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'bpm'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '12'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'breaths/min'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '122'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '66'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:09:35

US3742301

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mmHg'	System	14 Jan 2021 21:09:35

US3742301

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:45

US3742301

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:45

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User closed query 'per CDM: response noted, field still requires yes or no response ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:33:37
Query 'per CDM: response noted, field still requires yes or no response ' answered with 'Per form this is N/A' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 17:58:04
User opened query 'per CDM: response noted, field still requires yes or no response ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 20:18:22
User closed query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 20:18:22
Query 'per CDM: please input yes or no for this field' answered with 'N/A - per document ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:10:53
User opened query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:43:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:38

US3742301

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered empty.	System	14 Jan 2021 18:04:38

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'mRNA-1273'	System	14 Jan 2021 21:10:02
DataPoint set to visible.	System	14 Jan 2021 18:03:59

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11:29'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '14 Jan 2021 11:29'	System	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'ONCE'	System	14 Jan 2021 21:10:02

US3742301

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 21:10:02

US3742301

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:36

US3742301

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:36

US3742301

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '10:53'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:36

US3742301

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '14 Jan 2021 10:53'	System	14 Jan 2021 18:03:36

US3742301

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:44

US3742301

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:44

US3742301

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '10:54'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:03:44

US3742301

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered '14 Jan 2021 10:54'	System	14 Jan 2021 18:03:44

US3742301

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

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:04:50

US3742301

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

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:55
User entered 'I'	System	14 Jan 2021 18:04:50

US3742301

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 19:24:05
	(b) (4), (b) (6)	

US3742301

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:05

US3742301

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:05

US3742301

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4)	27 Jan 2021 19:24:05
	(b) (4), (b) (6)	

US3742301

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:13

US3742301

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User entered 'I'	System	27 Jan 2021 19:24:13

US3742301

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:21
User entered 'I'	System	27 Jan 2021 19:24:13
DataPoint set to visible.	System	27 Jan 2021 19:24:13

US3742301

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:54:41

US3742301

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:54:41

US3742301

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[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 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:54:41

US3742301

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'OLD29'	System	11 Feb 2021 16:54:41

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '10:55'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered '11 Feb 2021 10:55'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '58'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'bpm'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'breaths/min'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '117'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'mmHg'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '70'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'mmHg'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11:45'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered '11 Feb 2021 11:45'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '55'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'bpm'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'breaths/min'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '120'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'mmHg'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '72'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'mmHg'	System	11 Feb 2021 16:59:30

US3742301

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:37

US3742301

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:59:37

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:52:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4) Kaitlin Mason (b) (4)	23 Feb 2021 13:23:05
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 18:00:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 13:23:00
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty; reason for change Data Entry Error	(b) (4)	23 Feb 2021 13:23:00
User entered '10:40'	Kaitlin Mason (b) (4)	23 Feb 2021 13:23:00
	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered empty.	System	23 Feb 2021 13:23:00
User entered '11 Feb 2021 10:40'	System	11 Feb 2021 16:55:03

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	11 Feb 2021 17:01:25
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	11 Feb 2021 17:01:25
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Feb 2021 17:01:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'mRNA-1273'	System	11 Feb 2021 17:01:16
DataPoint set to visible.	System	27 Jan 2021 19:24:13

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '11:13'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered '11 Feb 2021 11:13'	System	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:25
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'ONCE'	System	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 17:01:16

US3742301

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:29

US3742301

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:07
User entered 'I'	System	11 Feb 2021 17:01:29

US3742301

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:26:31

US3742301

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '19 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:26:31

US3742301

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:26:31

US3742301

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 14:26:31

US3742301

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:26:52

US3742301

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:54:37
User entered 'I'	System	23 Feb 2021 14:26:52

US3742301

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:00

US3742301

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:00

US3742301

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:00

US3742301

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered 'OLD57'	System	25 Mar 2021 16:39:00

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered empty.	System	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered empty.	System	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered empty.	System	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered empty.	System	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered empty.	System	25 Mar 2021 16:39:15

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27

US3742301

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27

US3742301

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:21

US3742301

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:21

US3742301

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:30

US3742301

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:30

US3742301

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '12:20'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:30

US3742301

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:27
User entered '25 Mar 2021 12:20'	System	25 Mar 2021 16:39:30

US3742301

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:37
User closed query 'Per CDA, per sponsor review: Previous CLR query response noted, however, 'Joint aches in several joints', 'Fatigue' and 'Headache' has not been recorded . Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Joint aches in several joints', 'Fatigue' and 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 17:57:37
Query 'Per CDA, per sponsor review: Previous CLR query response noted, however, 'Joint aches in several joints', 'Fatigue' and 'Headache' has not been recorded . Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Joint aches in several joints', 'Fatigue' and 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'AE recorded for headache and fatigue. however, joint aches as per diary lasted only 6 days. no ae required ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:54:54

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDA, per sponsor review: Previous CLR query response noted, however, 'Joint aches in several joints', 'Fatigue' and 'Headache' has not been recorded . Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Joint aches in several joints', 'Fatigue' and 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:32:10
Query 'Per CDA, per sponsor review: Previous CLR query response noted, however, 'Joint aches in several joints', 'Fatigue' and 'Headache' gas not been recorded . per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 2, 'Joint aches in several joints', 'Fatigue' and 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' canceled (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:31:09
User opened query 'Per CDA, per sponsor review: Previous CLR query response noted, however, 'Joint aches in several joints', 'Fatigue' and 'Headache' gas not been recorded . per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 2, 'Joint aches in several joints', 'Fatigue' and 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:30:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:34:29

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 10), symptom of HEADACHE persist beyond Day 7 (start date: Day 2; end date: Day 8), symptom of JOINT ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8), symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 9) and Per Diary Dose 2 Record, symptom of CHILLS persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 15:24:22
	(b) (4), (b) (6)	23 Feb 2021 19:18:35
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 10), symptom of HEADACHE persist beyond Day 7 (start date: Day 2; end date: Day 8), symptom of JOINT ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8), symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 9) and Per Diary Dose 2 Record, symptom of CHILLS persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'ae recorded ' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:38:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 08:11:16
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Kaitlin Mason (b) (4)	19 Nov 2020 17:12:10
' answered with 'no - continued reactogenicity ' (Site from DM).	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	18 Nov 2020 19:05:56
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:57:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:57:41
Data point term sent to Coder	System	23 Oct 2020 19:56:05
User entered 'chills'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '9 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '12:41'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
User entered '9 Oct 2020 12:41'	System	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '16 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '12:00'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
User entered '16 Oct 2020 12:00'	System	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4)	
	Kaitlin Mason (b) (4)	19 Nov 2020 17:12:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:05:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Oct 2020 19:05:31
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:05:31
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Oct 2020 19:56:01
User entered '0'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:56:01

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 19:58:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 19:58:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Hassan Haji (b) (4)	23 Oct 2020 19:58:40
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:56:01
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01
	(b) (4)	

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[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 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:56:01

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
User entered '0'	System	27 Oct 2020 19:05:31

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10
User entered '0'	System	27 Oct 2020 19:05:31

US3742301

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:10

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:04:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:04:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 19:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 19:59:43
Data point term sent to Coder	System	23 Oct 2020 19:59:08
User entered 'muscle aches'	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '10 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
User entered empty.	System	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '16 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
User entered empty.	System	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:06:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:58:21
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Oct 2020 19:06:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:06:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Oct 2020 19:58:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[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 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
User entered '0'	System	27 Oct 2020 19:06:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12
User entered '0'	System	27 Oct 2020 19:06:23

US3742301

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:12

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 14:22:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 13:46:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 13:46:30
Data point term sent to Coder	System	30 Dec 2020 13:45:32
Query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'generalized joint pain added to indicate location ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 13:45:05
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 13:44:48
User entered 'Generalized JOINT PAIN' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Dec 2020 13:44:48
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 13:22:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:01:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:01:32
Data point term sent to Coder	System	23 Oct 2020 20:00:10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'joint pain'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '14 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
User entered empty.	System	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '17 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
User entered empty.	System	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

US3742301

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 19:07:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 19:07:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 19:59:47
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Oct 2020 19:07:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:07:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Oct 2020 19:59:47
User entered '0'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[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 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:59:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
User entered '0'	System	27 Oct 2020 19:07:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19
User entered '0'	System	27 Oct 2020 19:07:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:44:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Oct 2020 12:26:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 12:26:17
Data point term sent to Coder	System	31 Oct 2020 12:25:09
User entered 'urinary tract infection'	Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '26 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
User entered empty.	System	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:38:12
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'End date added' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 13:46:41
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 13:46:21
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 13:22:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '03 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 13:46:21
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
User entered empty.	System	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Hassan Haji (b) (4)	31 Oct 2020 12:24:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	31 Oct 2020 12:24:48
User entered '1' reason for change: Data Entry Error	Hassan Haji (b) (4)	31 Oct 2020 12:24:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	31 Oct 2020 12:24:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:46:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Hassan Haji (b) (4) (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
User entered '0'	System	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58
User entered '0'	System	31 Oct 2020 12:24:42

US3742301

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 12:35:27
User entered 'USA-US127-2021-mRNA-1273-P301000009'	System	04 Feb 2021 12:35:23
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 12:35:23

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Internal hernia, LLT: Internal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 14:19:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 14:19:00
Data point term sent to Coder	System	23 Feb 2021 14:18:09
Coding entries removed.	Sherry McCammon (b) (4)	23 Feb 2021 14:17:43
User entered 'internal hernia' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	23 Feb 2021 14:17:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Volvulus, LLT: Volvulus - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 18:27:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 18:27:37
Data point term sent to Coder	System	03 Feb 2021 18:27:15
User entered 'Volvulus'	(b) (4), (b) (6)	03 Feb 2021 18:26:20

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4)	03 Feb 2021 18:26:20
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 18:26:20

US3742301

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 14:19:10
User entered '17 Jan 2021'	Sherry McCammon (b) (4)	23 Feb 2021 14:19:10
	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4)	03 Feb 2021 18:26:20
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:38:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'updated discharge date' (Site from Safety).	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:21:31
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:38:10
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4)	03 Feb 2021 18:26:20
	(b) (4), (b) (6)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 22:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 22:15:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 18:26:20
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 22:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 22:15:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 18:26:20
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:38:53
	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 15:36:48
	(b) (4)	
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 22:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 22:15:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 18:26:20
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:50:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'subject had a concomitant procedure . no medication ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:00:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 17:27:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:39:02
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:55:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'request for records submitted' (Site from Safety).	Kaitlin Mason (b) (4)	23 Feb 2021 15:35:53
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:38:53
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 16:20:23
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 16:20:23
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:20:23
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:20

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Records still not received. 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 Apr 2021 15:47:36
Query 'PV Query: Records still not received. 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 'records sent again 4/23/2021' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 20:29:30
User opened query 'PV Query: Records still not received. 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)	23 Apr 2021 15:36:01
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)	23 Apr 2021 15:36:01

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
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 'documents send previously' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	22 Apr 2021 17:53:45
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) (b) (4)	22 Apr 2021 13:11:06
User closed query 'Per DM CLR: Narrative indicates that subject had "BOWEL RESECTION RESECTION". However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	16 Apr 2021 09:01:02
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	13 Apr 2021 21:46:11
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) (b) (4)	13 Apr 2021 19:51:12
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) (b) (4)	13 Apr 2021 19:51:02

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that subject had "BOWEL RESECTION RESECTION". However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated - see con procedures for appropriately documented procedure ' (Site from DM). DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	12 Apr 2021 20:22:00
Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	12 Apr 2021 20:20:26
User entered 'CONTACT PARTICIPANT TODAY FOR DAY 149 SAFETY AND SHE INFORMED US THAT SHE HAD BEEN ADMITTED WITH "TWISTED INTESTINES". SHE HAD SURGERY WITH REPORTEDLY BOWEL RESECTION RESECTION. ADMITTED 16JAN2021 TO 22JAN2021. Addendum - according to hospital records participant did not have have bowel resection but had a laparoscopic internal hernia repair.' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Apr 2021 20:20:26
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 'POCT COVID Testing was done 18 January 2021 and resulted negative' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	12 Apr 2021 20:13:46
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 'sent feb 3rd 2021' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:10:16

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
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)	23 Mar 2021 17:27:43
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)	23 Mar 2021 17:22:39
User opened query 'Per DM CLR: Narrative indicates that subject had "BOWEL RESECTION RESECTION". However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 05:27:08
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)	24 Feb 2021 15:39:12
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)	24 Feb 2021 15:39:08
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
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 'unknown at this time ' (Site from Safety).	Kaitlin Mason (b) (4)	23 Feb 2021 15:36:32

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[Narrative](#)

Audit	User	Time (GMT)
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 'records requested - not received at this time ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	23 Feb 2021 15:36:25
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)	10 Feb 2021 19:39:13
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)	10 Feb 2021 19:38:41
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 18:42:12
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Feb 2021 18:42:12
User entered 'Contact participant today for Day 149 safety and she informed us that she had been admitted with "twisted intestines". She had surgery with reportedly bowel resection resection. Admitted 16Jan2021 to 22Jan2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 18:42:12
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 18:26:20
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:26:20

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Form: Adverse Events (5)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 18:26:20

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Form: Adverse Events (5)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 18:26:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:45:45
Data point term sent to Coder	System	20 Apr 2021 20:45:05
User entered 'HEADACHE'	(b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:53:19
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 20:46:33
User entered '12:29' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:46:33
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 20:44:43
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User entered '10 Sep 2020 12:29'	System	20 Apr 2021 20:46:33
User entered empty.	System	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 20:47:54
User entered '12:57' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:47:54
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 20:44:43
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User entered '17 Sep 2020 12:57'	System	20 Apr 2021 20:47:54
User entered empty.	System	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Apr 2021 20:46:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 20:46:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	20 Apr 2021 20:46:33
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 20:44:43
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User entered '0'	System	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05
User entered '0'	System	20 Apr 2021 20:44:43

US3742301

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:05

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:54:36
Data point term sent to Coder	System	20 Apr 2021 20:53:13
User entered 'FATIGUE'	(b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '23:00'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User entered '09 Sep 2020 23:00'	System	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '12:00'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User entered '18 Sep 2020 12:00'	System	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User entered '0'	System	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09
User entered '0'	System	20 Apr 2021 20:52:46

US3742301

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User closed query 'Per CDM. "To treat pain or fever that has already occurred" is answered as YES on Day 2, however no medications are entered for this day. Please review and update medications or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:05:14
Query 'Per CDM. "To treat pain or fever that has already occurred" is answered as YES on Day 2, however no medications are entered for this day. Please review and update medications or clarify otherwise. Thank you!' answered with 'ALL ENTRIES FOR HEADACHE AND FATIGUE WERE RELATED TO MENSTRUAL CYCLE. ALL OTHER ENTRIES FOR MUSCLE AND JOINT ACHES, NAUSEA AND VOMITING, AND CHILLS WERE ALL ENTERED INCORRECTLY. DID NOT REPORT MEDS DURING DAY 8 CALL. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	28 Sep 2020 13:43:17
User opened query 'Per CDM. "To treat pain or fever that has already occurred" is answered as YES on Day 2, however no medications are entered for this day. Please review and update medications or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:13:46
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:13:13

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 08:43:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:43:43
Data point term sent to Coder	System	11 Sep 2020 13:16:28
User entered 'Isinopril'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:16:19

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'hypertension'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '20'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'UN May 2019'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:16:19
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:16:19

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:16:19

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:16:19

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 13:27:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:27:34
Data point term sent to Coder	System	11 Sep 2020 13:26:48
User entered 'hydrochlorothiazide'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:25:49

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'hypertension'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '25'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'UN Jul 2019'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:25:49
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:25:49

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:25:49

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:25:49

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
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 13:23:43
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 13:23:43
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.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:07:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:07:40
Data point term sent to Coder	System	11 Sep 2020 13:29:53
User entered 'iron'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 13:29:35

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'menorrhagia'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'capsule (CAPSULE)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'UN UNK 2017'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 13:29:35
	(b) (4)	

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:29:35

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:29:35

US3742301

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:29:35

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:31:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:37
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:20:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 18:20:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	23 Feb 2021 14:25:18

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:34:49
User entered '18 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 18:21:45

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:20:05
User entered 'LAPAROSCOPY INTERNAL HERNIA REPAIR' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:20:05
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:34:49
	(b) (4)	
User entered 'Internal hernia repair'	(b) (4), (b) (6)	08 Mar 2021 18:21:45

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:34:49
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:16:35
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'Updated to match AE entry. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:21:04
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:55:41
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	08 Mar 2021 18:21:45

US3742301

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:42

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:34:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 18:21:45

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'USA-US127-2021-MRNA-1273-P301000009'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Karen'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Kotloff'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Baltimore'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '21201'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 19:53:06
User entered '3'	System	24 Mar 2021 13:57:00
Signature has been broken.	System	24 Feb 2021 15:39:42
User entered '2'	System	24 Feb 2021 15:39:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'USA-US127-2021-MRNA-1273-P301000009'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Karen'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Kotloff'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Baltimore'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '21201'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 19:53:06
User entered '3'	System	24 Mar 2021 13:57:00
Signature has been broken.	System	24 Feb 2021 15:39:42
User entered '2'	System	24 Feb 2021 15:39:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered '04/Feb/2021 10:06'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:42

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)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'USA-US127-2021-MRNA-1273-P301000009'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Karen'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Kotloff'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Baltimore'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '21201'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 19:53:06
User entered '3'	System	24 Mar 2021 13:57:00
Signature has been broken.	System	24 Feb 2021 15:39:42
User entered '2'	System	24 Feb 2021 15:39:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:43
User entered '24/Feb/2021 10:39'	System	24 Feb 2021 15:39:42

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:42

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 21:35:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:56:41
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:28:43
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 15:39:42

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'USA-US127-2021-MRNA-1273-P301000009'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Karen'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Kotloff'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Baltimore'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '21201'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 19:53:06
User entered '3'	System	24 Mar 2021 13:57:00
Signature has been broken.	System	24 Feb 2021 15:39:42
User entered '2'	System	24 Feb 2021 15:39:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered '24/Mar/2021 08:56'	(b) (4) System	24 Mar 2021 13:57:00

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:42

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 19:52:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:35:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:57:00

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'USA-US127-2021-MRNA-1273-P301000009'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Yes (Y)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'No (N)'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Karen'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Kotloff'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered 'Baltimore'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:06:01
User entered '21201'	System	04 Feb 2021 12:35:23

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:09:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
User entered 'US'	(b) (4) System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 19:53:06
User entered '3'	System	24 Mar 2021 13:57:00
Signature has been broken.	System	24 Feb 2021 15:39:42
User entered '2'	System	24 Feb 2021 15:39:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:55:50
	(b) (4)	
User entered '1'	System	04 Feb 2021 15:06:07

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:46:11
User entered '13/Apr/2021 15:53'	(b) (4) System	13 Apr 2021 19:53:06

US3742301

Folder: SAE USA-US127-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:42

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 21:46:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:53:06