

US3742342 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:33:36

All time stamps listed in this document are displayed in GMT

US3742342

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

[Participant ID](#)

US3742342

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

US3742342

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

Date of Birth (MMM yyyy)	(b) (6) 2002
Age	18
Age Units	YEARS
Age (Derived)	18
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

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 17:45:49

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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 17:45:49

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Condition	CHILDHOOD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2008
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 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:45:49

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:45
Height (xxx.x)	59.0 in
Weight (xxx.x)	125.0 lb
BMI (xxx.x)	25.29973 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 17:45:49

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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 17:45:49

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Date of assessment (dd MMM yyyy) 11 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 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 17:45:49

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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

WORK AT LAW FIRM

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 17:45:49

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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 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113350

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 17:45:49

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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 17:45:49

Generated On: 10 Jun 2021 09:33:36

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:41 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:41
Temperature (xxx.x)	097.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	098 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:08
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	090 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 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 17:45:49

Generated On: 10 Jun 2021 09:33:36

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 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:36 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:36

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 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	15:52 (24 HR)
Collection date and time (derived)	11 SEP 2020 15:52

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	11 SEP 2020 15:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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 09:33:36

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

98.7 °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

11 SEP 2020 17:27

PC Open Date & Time

11 SEP 2020 16:56

PC Close Date & Time

11 SEP 2020 19:26

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 97.3 °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	11 SEP 2020 22:07
PC Open Date & Time	11 SEP 2020 20:21
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

12 SEP 2020 12:51

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

13 SEP 2020 23:35

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

98.1 °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 SEP 2020 23:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 00:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

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

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 00:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

11 SEP 2020 17:27

PC Open Date & Time

11 SEP 2020 16:56

PC Close Date & Time

11 SEP 2020 19:26

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

11 SEP 2020 22:08

PC Open Date & Time

11 SEP 2020 20:21

PC Close Date & Time

12 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

12 SEP 2020 12:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

13 SEP 2020 23:36

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

14 SEP 2020 23:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

16 SEP 2020 00:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 ☐

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.**

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

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

18 SEP 2020 00:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:27
PC Open Date & Time	11 SEP 2020 16:56
PC Close Date & Time	11 SEP 2020 19:26

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:08
PC Open Date & Time	11 SEP 2020 20:21
PC Close Date & Time	12 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 ☒

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

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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EAB) (1725)

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US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:36
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:37
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 ☒

PRODUCTION RELEASE (v12.003

52 of 1923

EAB) (1725)

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1923

EAB) (1725)

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 00:59
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3742342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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 OCT 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:35
Temperature (xxx.x)	098.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 12:04
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	070 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 09 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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) 09 OCT 2020

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 11:33

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

US3742342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	09 OCT 2020 10:46

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	09 OCT 2020 10:40
Nasopharyngeal Swab 2	No		

US3742342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

98.6 °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

09 OCT 2020 12:07

PC Open Date & Time

09 OCT 2020 11:53

PC Close Date & Time

09 OCT 2020 14:23

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 97.1 °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	10 OCT 2020 09:43
PC Open Date & Time	09 OCT 2020 15:18
PC Close Date & Time	10 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

11 OCT 2020 01:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 11:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 23:59

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 08:04

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 00:07

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 00:00

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:08

PC Open Date & Time

09 OCT 2020 11:53

PC Close Date & Time

09 OCT 2020 14:23

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

10 OCT 2020 09:43

PC Open Date & Time

09 OCT 2020 15:18

PC Close Date & Time

10 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

11 OCT 2020 01:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

12 OCT 2020 11:54

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 OCT 2020 23:59

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

14 OCT 2020 08:06

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

15 OCT 2020 00:07

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

16 OCT 2020 00:01

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 12:09
PC Open Date & Time	09 OCT 2020 11:53
PC Close Date & Time	09 OCT 2020 14:23

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

No ☒

Yes ☐

PC Time stamp	10 OCT 2020 09:45
PC Open Date & Time	09 OCT 2020 15:18
PC Close Date & Time	10 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 ☒

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 01:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 11:54
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 ☒

PRODUCTION RELEASE (v12.003

97 of 1923

EAB) (1725)

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 23:59
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 ☒

PRODUCTION RELEASE (v12.003

99 of 1923

EAB) (1725)

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 08:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 00:07
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 ☒

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 00:01
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3742342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

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) _____

US3742342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3742342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 NOV 2020

Collection time (00:00-23:59)

12:06 (24 HR)

Collection date and time (derived)

6 NOV 2020 12:06

US3742342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:45:49

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

11 NOV 2020 00:33:39

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

18 NOV 2020 00:01:43

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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	24 NOV 2020 18:30:25
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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	29 NOV 2020 00:19:11
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 DEC 2020 17:59:21
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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	17 DEC 2020 11:59:25
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

20 DEC 2020 11:33:34

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

30 DEC 2020 19:07:10

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

05 JAN 2021 14:05:10

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 <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	14 JAN 2021 12:03:55
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

24 JAN 2021 01:22:03

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

04 FEB 2021 12:01:19

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 152

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 <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	14 FEB 2021 00:08:02
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

23 FEB 2021 12:27:24

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

02 MAR 2021 18:16:03

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 14:32:45

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

17 MAR 2021 19:38:48

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

21 MAR 2021 00:02:22

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

28 MAR 2021 00:17:56

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

04 APR 2021 00:02:33

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

15 APR 2021 11:59:14

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

18 APR 2021 00:10:01

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

25 APR 2021 00:55:42

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

02 MAY 2021 14:49:34

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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="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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	06 NOV 2022 00:01
Patient Cloud Close Date & Time	10 NOV 2022 23:59

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

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

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3742342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:33:36

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		02 MAR 2021 18:16:13

US3742342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

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) _____

US3742342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

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.

US3742342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 MAR 2021

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

27 MAR 2021 09:35

US3742342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742342

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:33:36

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"/>

US3742342

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:33:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742342

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

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

Visit date (dd MMM yyyy)	21 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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US3742342

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:47:52

Generated On: 10 Jun 2021 09:33:36

Date of updated informed consent (<i>dd MMM yyyy</i>)	21 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>)	21 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

US3742342

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

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

US3742342

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

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)	21 JAN 2021
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 09:35
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	093 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

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)	21 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 10:20
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	086 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3742342

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	21 JAN 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)	

US3742342

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

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) 21 JAN 2021

What was the treatment time? (00:00-23:59) 09:47 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 09:47

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

US3742342

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

09:12 (24 HR)

Collection date and time (derived)

21 JAN 2021 09:12

US3742342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	09:17
Collection Date and Time (derived)	21 JAN 2021 09:17

US3742342

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

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)	27 FEB 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	27 FEB 2021 10:26
Temperature (xxx.x)	098.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	091 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

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)	27 FEB 2021
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	27 FEB 2021 11:21
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 mmHg
Diastolic Blood Pressure units	MMHG

US3742342

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 FEB 2021

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

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	27 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)	

US3742342

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

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) 27 FEB 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 27 FEB 2021 10:50

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

US3742342

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742342

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3742342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3742342

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

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.

US3742342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3742342

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

AEID	USA-US127-2020-MRNA-1273-P30 1000001
Adverse event	MAJOR DEPRESSIVE DISORDER WITHOUT PSYCHOTIC FEATURES
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 SEP 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)	17 SEP 2020
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 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	17 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	349 of 1923

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input checked="" type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

VOLUNTEER WAS CONTACTED
FOR A DAY 8 PHONE CALL
POST 1ST VACCINATION ON
18SEP2020. WHEN ASKED
ABOUT NOT COMPLETING HER
DIARY, SHE REPORTED THAT
SHE COULDN'T DO IT BECAUSE
SHE WAS HOSPITALIZED DUE
TO "SOME EMOTIONAL
DIFFICULTIES." MEDICAL
RECORDS WERE REQUESTED
AND RECEIVED. PER HOSPITAL
DOCUMENTATION SHE
PRESENTED WITH HISTORY OF
DEPRESSION WITH INCREASED
THOUGHTS OF HARMING
HERSELF ON AND OFF FOR
MONTHS. FURTHER, THE
DOCUMENTATION STATED
THAT THE DIAGNOSIS WAS
SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER,
WITHOUT PSYCHOTIC
FEATURES. NO MEDICATIONS
WERE TAKEN.

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

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

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

Yes ☒

No ☐

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

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Name of Medication LEVORA

Prophylaxis Yes ☐
No ☒

Indication BIRTH CONTROL

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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US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	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"/>

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	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)	19 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Name of Medication STRATTERA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 (4)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	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)	14 JAN 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"/>

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 18:04:16

Generated On: 10 Jun 2021 09:33:36

	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 OCT 2020	
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"/>

US3742342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:38:48

Generated On: 10 Jun 2021 09:33:36

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3742342

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:33:36

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

US3742342

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:33:36

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 ☐

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

SAEID	USA-US127-2020-MRNA-1273-P301000001
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)	3

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

SAEID	USA-US127-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:54
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

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

SAEID	USA-US127-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:58
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

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 18:05:27

Generated On: 10 Jun 2021 09:33:36

SAEID	USA-US127-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:13
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

US3742342 (Prod: University of Maryland School of Medicine)

US3742342

Form: Participant Creation

Generated On: 10 Jun 2021 09:33:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'US3742342'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:24:35

US3742342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:57:18

US3742342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:24:36

US3742342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	11 Sep 2020 20:57:18

US3742342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'SCRN'	System	11 Sep 2020 20:57:18

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered (b) (6) 2002'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:24:37

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '18'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'YEARS'	System	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '18'	System	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Female (F)'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'I'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:33:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:57:49

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'Sep 2020'	System	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '2020'	System	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:04

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:24:36

US3742342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:33:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'I'	System	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:33:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:12:23

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Childhood asthma, LLT: Childhood asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 15:14:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 15:14:54
Data point term sent to Coder	System	12 Sep 2020 15:13:49
User entered 'childhood asthma'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered 'UN UNK 2008'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered 'UN UNK 2013'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'Jan 2008'	System	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '2008'	System	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'Jan 2013'	System	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '2013'	System	12 Sep 2020 15:13:42

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:15:53
Data point term sent to Coder	System	19 Sep 2020 19:14:35
User entered 'DEPRESSION'	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered 'UN UNK 2013'	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered '0'	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:59:44
User entered '0'	(b) (4), (b) (6)	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'Jan 2013'	System	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '2013'	System	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	19 Sep 2020 19:14:17

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '15:45'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '11 Sep 2020 15:45'	System	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	29 Sep 2020 18:59:16
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	29 Sep 2020 18:59:16
User entered '59.0' in reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:59:16
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	29 Sep 2020 18:58:51
User entered '125.0' in	(b) (4), (b) (6)	29 Sep 2020 18:58:51
DataPoint set to visible.	System	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4)	29 Sep 2020 18:59:16
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	29 Sep 2020 18:59:16
User entered '125.0' lb reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:59:16
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	29 Sep 2020 18:58:51
User entered '59.0' lb	(b) (4), (b) (6)	29 Sep 2020 18:58:51
DataPoint set to visible.	System	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '25.29973'	System	29 Sep 2020 18:59:16
User entered '2.66037'	System	29 Sep 2020 18:58:51
DataPoint set to visible.	System	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'kg/m2'	System	29 Sep 2020 18:58:51
DataPoint set to visible.	System	11 Sep 2020 20:58:08

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'bpm'	System	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'breaths/min'	System	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	29 Sep 2020 18:58:51

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33

US3742342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33

US3742342

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:57:47

US3742342

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:57:47

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:33:36

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	12 Sep 2020 15:14:43

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	29 Sep 2020 18:59:51

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'work at law firm'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'I'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:33:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:58:49

US3742342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:15:18

US3742342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:15:18

US3742342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	12 Sep 2020 15:15:18

US3742342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'VISIT1'	System	12 Sep 2020 15:15:18

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:24:17

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '113350'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:24:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:24:17

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:16:07

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:16:07

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:16:07

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:16:07

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:16:07

US3742342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:15:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:15:23

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4)	29 Sep 2020 13:20:01
Query 'per CDM RQ: please input ND into height and weight' answered with 'DATA HAS BEEN REMOVED AND ND HAS BEEN ADDED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:29:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:28:47
User opened query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:13:42
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) (6)	28 Sep 2020 17:13:42
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 17:49:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:49:15
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 13:13:48
User entered '59.0' in	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:49:15
User entered '125.0' lb	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4)	29 Sep 2020 13:20:01
Query 'per CDM RQ: please input ND into height and weight' answered with 'DATA HAS BEEN REMOVED AND ND HAS BEEN ADDED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:29:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:28:47
User opened query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:13:42
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) (6)	28 Sep 2020 17:13:42
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 17:49:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:49:15
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 13:13:48
User entered '59.0' in	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:49:15
User entered '125.0' lb	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '15:41'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '11 Sep 2020 15:41'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '097.2' F	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Other (Other)'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'temporal'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '098'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'bpm'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '14'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'breaths/min'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '127'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'mmHg'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '087'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'mmHg'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4)	
Query 'per CDM RQ: please input ND into height and weight' answered with 'DATA HAS BEEN REMOVED AND ND HAS BEEN ADDED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:20:01
Query 'per CDM RQ: please input ND into height and weight' answered with 'DATA HAS BEEN REMOVED AND ND HAS BEEN ADDED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:29:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:28:47
User opened query 'per CDM RQ: please input ND into height and weight' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:13:42
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) (6)	28 Sep 2020 17:13:42
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.'	(b) (4), (b) (6)	22 Sep 2020 17:49:29
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.'	(b) (4), (b) (6)	22 Sep 2020 17:49:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 13:13:48
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.'	(b) (4), (b) (6)	21 Sep 2020 13:13:48
User entered '59.0' in	Hassan Haji (b) (4)	12 Sep 2020 15:21:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:49:15
User entered '125.0' lb	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '17:08'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '11 Sep 2020 17:08'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '99.3' F	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '090'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'bpm'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '14'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'breaths/min'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '124'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'mmHg'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '087'	Hassan Haji (b) (4)	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'mmHg'	System	12 Sep 2020 15:21:54

US3742342

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'Per CDM: Subject was screened and dosed on same day and duplicate data have been recorded on the Physical Examination and Pregnancy test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the physical examination and pregnancy test performed?' to No at Visit 1 Day 1 and Yes at Screening, if a second test was not performed. Alternatively, please explain' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:35:06
Query 'Per CDM: Subject was screened and dosed on same day and duplicate data have been recorded on the Physical Examination and Pregnancy test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the physical examination and pregnancy test performed?' to No at Visit 1 Day 1 and Yes at Screening, if a second test was not performed. Alternatively, please explain' answered with 'ENTERED IN ERROR UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:28:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:27:47
User opened query 'Per CDM: Subject was screened and dosed on same day and duplicate data have been recorded on the Physical Examination and Pregnancy test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the physical examination and pregnancy test performed?' to No at Visit 1 Day 1 and Yes at Screening, if a second test was not performed. Alternatively, please explain' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 10:30:09
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:23:13

US3742342

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:27:47
User entered '11 Sep 2020'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:23:13

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered empty.	System	12 Sep 2020 15:23:44

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '16:36'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '11 Sep 2020 16:36'	System	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'ONCE'	System	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 21:01:18

US3742342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:24:07

US3742342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:24:07

US3742342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '15:52'	Hassan Haji (b) (4)	12 Sep 2020 15:24:07

US3742342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '11 Sep 2020 15:52'	System	12 Sep 2020 15:24:07

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:33:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11 Sep 2020'	Hassan Haji (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '15:50'	Hassan Haji (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '11 Sep 2020 15:50'	System	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered empty.	System	12 Sep 2020 15:24:35

US3742342

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 15:24:40

US3742342

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	12 Sep 2020 15:24:40

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:26:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e0f95ce0-25d5-4630-b6c9-2d80155dbea2' User entered 'Yes (Y)'	System	11 Sep 2020 21:27:28
	System	11 Sep 2020 21:27:28

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:26:41', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e0f95ce0-25d5-4630-b6c9-2d80155dbea2' User entered '98.7'	System	11 Sep 2020 21:27:28
	System	11 Sep 2020 21:27:28

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:26:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e0f95ce0-25d5-4630-b6c9-2d80155dbea2'	System	11 Sep 2020 21:27:28
User entered 'No (N)'	System	11 Sep 2020 21:27:28

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:09', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e0f95ce0-25d5-4630-b6c9-2d80155dbea2'	System	11 Sep 2020 21:27:28
User entered '11 Sep 2020 17:27'	System	11 Sep 2020 21:27:28

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 16:56'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 19:26'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:07:32', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8af8f553-a2ed-4ccd-8ccc-94637640fc5a' User entered 'Yes (Y)'	System	12 Sep 2020 02:07:45
	System	12 Sep 2020 02:07:45

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:07:36', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8af8f553-a2ed-4ccd-8ccc-94637640fc5a' User entered '97.3'	System	12 Sep 2020 02:07:45
	System	12 Sep 2020 02:07:45

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:07:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8af8f553-a2ed-4ccd-8ccc-94637640fc5a'	System	12 Sep 2020 02:07:45
User entered 'No (N)'	System	12 Sep 2020 02:07:45

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:07:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8af8f553-a2ed-4ccd-8ccc-94637640fc5a'	System	12 Sep 2020 02:07:45
User entered '11 Sep 2020 22:07'	System	12 Sep 2020 02:07:45

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 20:21'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 2'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:50:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3e2fde80-906f-442d-a7f7-98241167381a' User entered 'Yes (Y)'	System	12 Sep 2020 16:51:50
	System	12 Sep 2020 16:51:50

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:51:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3e2fde80-906f-442d-a7f7-98241167381a' User entered '98.6'	System	12 Sep 2020 16:51:50
	System	12 Sep 2020 16:51:50

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:51:46', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3e2fde80-906f-442d-a7f7-98241167381a' User entered 'No (N)'	System	12 Sep 2020 16:51:50
	System	12 Sep 2020 16:51:50

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:51:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3e2fde80-906f-442d-a7f7-98241167381a' User entered '12 Sep 2020 12:51'	System	12 Sep 2020 16:51:50
	System	12 Sep 2020 16:51:50

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 3'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:34:39', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '80e0148f-929c-4bf8-b65a-d94ac3f367b6' User entered 'Yes (Y)'	System	14 Sep 2020 03:35:55
	System	14 Sep 2020 03:35:55

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '80e0148f-929c-4bf8-b65a-d94ac3f367b6' User entered '98.1'	System	14 Sep 2020 03:35:55
	System	14 Sep 2020 03:35:55

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:46', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '80e0148f-929c-4bf8-b65a-d94ac3f367b6'	System	14 Sep 2020 03:35:55
User entered 'No (N)'	System	14 Sep 2020 03:35:55

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:50', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '80e0148f-929c-4bf8-b65a-d94ac3f367b6' User entered '13 Sep 2020 23:35'	System	14 Sep 2020 03:35:55
	System	14 Sep 2020 03:35:55

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 4'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:35:18', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4e9a212f-0f36-49db-976c-8f3c08d22067' User entered 'Yes (Y)'	System	15 Sep 2020 03:36:32
	System	15 Sep 2020 03:36:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4e9a212f-0f36-49db-976c-8f3c08d22067' User entered '98.1'	System	15 Sep 2020 03:36:32
	System	15 Sep 2020 03:36:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:27', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4e9a212f-0f36-49db-976c-8f3c08d22067'	System	15 Sep 2020 03:36:32
User entered 'No (N)'	System	15 Sep 2020 03:36:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:30', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4e9a212f-0f36-49db-976c-8f3c08d22067' User entered '14 Sep 2020 23:36'	System	15 Sep 2020 03:36:32
	System	15 Sep 2020 03:36:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 5'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-15T23:59:19', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd29628d2-c625-4c48-82ff-a2041d64fead' User entered 'Yes (Y)'	System	16 Sep 2020 04:00:48
	System	16 Sep 2020 04:00:48

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:28', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd29628d2-c625-4c48-82ff-a2041d64fead' User entered '97.6'	System	16 Sep 2020 04:00:48
	System	16 Sep 2020 04:00:48

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:30', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd29628d2-c625-4c48-82ff-a2041d64fead'	System	16 Sep 2020 04:00:48
User entered 'No (N)'	System	16 Sep 2020 04:00:48

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:32', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd29628d2-c625-4c48-82ff-a2041d64fead' User entered '16 Sep 2020 00:00'	System	16 Sep 2020 04:00:48
	System	16 Sep 2020 04:00:48

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 6'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 7'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca4ef236-3ace-44f6-b5c0-3286b62abb18' User entered 'Yes (Y)'	System	18 Sep 2020 04:59:32
	System	18 Sep 2020 04:59:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca4ef236-3ace-44f6-b5c0-3286b62abb18' User entered '97.8'	System	18 Sep 2020 04:59:32
	System	18 Sep 2020 04:59:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:22', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca4ef236-3ace-44f6-b5c0-3286b62abb18'	System	18 Sep 2020 04:59:32
User entered 'No (N)'	System	18 Sep 2020 04:59:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca4ef236-3ace-44f6-b5c0-3286b62abb18' User entered '18 Sep 2020 00:59'	System	18 Sep 2020 04:59:32
	System	18 Sep 2020 04:59:32

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:15', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '774c9f61-99ba-4ca3-b29e-b69c847f3434'	System	11 Sep 2020 21:28:00
User entered 'None (1)'	System	11 Sep 2020 21:28:00

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:17', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '774c9f61-99ba-4ca3-b29e-b69c847f3434' User entered 'No (N)'	System	11 Sep 2020 21:28:00
	System	11 Sep 2020 21:28:00

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '774c9f61-99ba-4ca3-b29e-b69c847f3434' User entered 'No (N)'	System	11 Sep 2020 21:28:00
	System	11 Sep 2020 21:28:00

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:22', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '774c9f61-99ba-4ca3-b29e-b69c847f3434'	System	11 Sep 2020 21:28:00
User entered 'None (1)'	System	11 Sep 2020 21:28:00

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:24', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '774c9f61-99ba-4ca3-b29e-b69c847f3434'	System	11 Sep 2020 21:28:00
User entered '11 Sep 2020 17:27'	System	11 Sep 2020 21:28:00

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 16:56'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 19:26'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:13', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '62355692-e5a0-49f3-a120-94473f4e7220'	System	12 Sep 2020 02:08:25
User entered 'None (1)'	System	12 Sep 2020 02:08:25

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '62355692-e5a0-49f3-a120-94473f4e7220'	System	12 Sep 2020 02:08:25
User entered 'No (N)'	System	12 Sep 2020 02:08:25

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:18', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '62355692-e5a0-49f3-a120-94473f4e7220' User entered 'No (N)'	System	12 Sep 2020 02:08:25
	System	12 Sep 2020 02:08:25

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '62355692-e5a0-49f3-a120-94473f4e7220'	System	12 Sep 2020 02:08:25
User entered 'None (1)'	System	12 Sep 2020 02:08:25

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:23', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '62355692-e5a0-49f3-a120-94473f4e7220' User entered '11 Sep 2020 22:08'	System	12 Sep 2020 02:08:25
	System	12 Sep 2020 02:08:25

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 20:21'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 2'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:13', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c17e6e0a-2538-4f54-94dc-24887584ecd4'	System	12 Sep 2020 16:52:44
User entered 'None (1)'	System	12 Sep 2020 16:52:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:22', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c17e6e0a-2538-4f54-94dc-24887584ecd4' User entered 'No (N)'	System	12 Sep 2020 16:52:44
	System	12 Sep 2020 16:52:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:24', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c17e6e0a-2538-4f54-94dc-24887584ecd4' User entered 'No (N)'	System	12 Sep 2020 16:52:44
	System	12 Sep 2020 16:52:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:26', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c17e6e0a-2538-4f54-94dc-24887584ecd4' User entered 'None (1)'	System	12 Sep 2020 16:52:44
	System	12 Sep 2020 16:52:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:43', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c17e6e0a-2538-4f54-94dc-24887584ecd4' User entered '12 Sep 2020 12:52'	System	12 Sep 2020 16:52:44
	System	12 Sep 2020 16:52:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 3'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '586f2799-56bb-40f3-91f9-87e47a54d8fc' User entered 'None (1)'	System	14 Sep 2020 03:36:03
	System	14 Sep 2020 03:36:03

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '586f2799-56bb-40f3-91f9-87e47a54d8fc' User entered 'No (N)'	System	14 Sep 2020 03:36:03
	System	14 Sep 2020 03:36:03

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:57', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '586f2799-56bb-40f3-91f9-87e47a54d8fc' User entered 'No (N)'	System	14 Sep 2020 03:36:03
	System	14 Sep 2020 03:36:03

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:35:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '586f2799-56bb-40f3-91f9-87e47a54d8fc' User entered 'None (1)'	System	14 Sep 2020 03:36:03
	System	14 Sep 2020 03:36:03

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:01', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '586f2799-56bb-40f3-91f9-87e47a54d8fc' User entered '13 Sep 2020 23:36'	System	14 Sep 2020 03:36:03
	System	14 Sep 2020 03:36:03

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 4'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:35', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba4e24c4-ec54-4442-abc2-9e4242198c46'	System	15 Sep 2020 03:36:44
User entered 'None (1)'	System	15 Sep 2020 03:36:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba4e24c4-ec54-4442-abc2-9e4242198c46' User entered 'No (N)'	System	15 Sep 2020 03:36:44
	System	15 Sep 2020 03:36:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:38', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba4e24c4-ec54-4442-abc2-9e4242198c46' User entered 'No (N)'	System	15 Sep 2020 03:36:44
	System	15 Sep 2020 03:36:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba4e24c4-ec54-4442-abc2-9e4242198c46' User entered 'None (1)'	System	15 Sep 2020 03:36:44
	System	15 Sep 2020 03:36:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba4e24c4-ec54-4442-abc2-9e4242198c46'	System	15 Sep 2020 03:36:44
User entered '14 Sep 2020 23:36'	System	15 Sep 2020 03:36:44

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 5'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:35', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'eedfdcae-e1cb-4b15-ac6d-399869ecd1b4'	System	16 Sep 2020 04:00:55
User entered 'None (1)'	System	16 Sep 2020 04:00:55

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:36', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'eedfdcae-e1cb-4b15-ac6d-399869ecd1b4' User entered 'No (N)'	System	16 Sep 2020 04:00:55
	System	16 Sep 2020 04:00:55

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'eedfdcae-e1cb-4b15-ac6d-399869ecd1b4' User entered 'No (N)'	System	16 Sep 2020 04:00:55
	System	16 Sep 2020 04:00:55

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:38', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'eedfdcae-e1cb-4b15-ac6d-399869ecd1b4'	System	16 Sep 2020 04:00:55
User entered 'None (1)'	System	16 Sep 2020 04:00:55

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'eedfdcae-e1cb-4b15-ac6d-399869ecd1b4' User entered '16 Sep 2020 00:00'	System	16 Sep 2020 04:00:55
	System	16 Sep 2020 04:00:55

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 6'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 7'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:28', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd9f7381a-80b5-4c80-bc91-bbf446defbe3'	System	18 Sep 2020 04:59:39
User entered 'None (1)'	System	18 Sep 2020 04:59:39

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:30', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd9f7381a-80b5-4c80-bc91-bbf446defbe3' User entered 'No (N)'	System	18 Sep 2020 04:59:39
	System	18 Sep 2020 04:59:39

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd9f7381a-80b5-4c80-bc91-bbf446defbe3' User entered 'No (N)'	System	18 Sep 2020 04:59:39
	System	18 Sep 2020 04:59:39

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:33', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd9f7381a-80b5-4c80-bc91-bbf446defbe3' User entered 'None (1)'	System	18 Sep 2020 04:59:39
	System	18 Sep 2020 04:59:39

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:35', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd9f7381a-80b5-4c80-bc91-bbf446defbe3' User entered '18 Sep 2020 00:59'	System	18 Sep 2020 04:59:39
	System	18 Sep 2020 04:59:39

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:46', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'None (0)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388' User entered 'No (N)'	System	11 Sep 2020 21:28:36
	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T17:27:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '3123b9e6-f16e-4a80-ac78-f94383f75388'	System	11 Sep 2020 21:28:36
User entered '11 Sep 2020 17:27'	System	11 Sep 2020 21:28:36

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 16:56'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 19:26'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:26', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:27', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:29', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:33', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:34', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279' User entered 'None (0)'	System	12 Sep 2020 02:08:42
	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279'	System	12 Sep 2020 02:08:42
User entered 'No (N)'	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-11T22:08:39', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2bfa004a-d6e3-460c-9a1f-18151544c279'	System	12 Sep 2020 02:08:42
User entered '11 Sep 2020 22:08'	System	12 Sep 2020 02:08:42

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Sep 2020 20:21'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 2'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:50', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:54', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'None (0)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:57', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7' User entered 'No (N)'	System	12 Sep 2020 16:53:02
	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-12T12:52:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9d8e48f2-cde6-48e4-9ee6-4eabf96be6d7'	System	12 Sep 2020 16:53:02
User entered '12 Sep 2020 12:52'	System	12 Sep 2020 16:53:02

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 3'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered 'None (0)'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:06', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509'	System	14 Sep 2020 03:36:18
User entered 'None (0)'	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:08', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered 'None (0)'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:10', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered 'None (0)'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:12', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered 'None (0)'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:13', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered 'None (0)'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:15', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509'	System	14 Sep 2020 03:36:18
User entered 'No (N)'	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-13T23:36:17', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '28fcbe12-eebf-4fb1-90a9-272a070cd509' User entered '13 Sep 2020 23:36'	System	14 Sep 2020 03:36:18
	System	14 Sep 2020 03:36:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 4'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'None (0)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'None (0)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'None (0)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:36:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'None (0)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:37:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5' User entered 'None (0)'	System	15 Sep 2020 03:37:52
	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:37:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'None (0)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:37:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered 'No (N)'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-14T23:37:49', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0f7b8388-3484-4728-97c5-8dd97b0714b5'	System	15 Sep 2020 03:37:52
User entered '14 Sep 2020 23:37'	System	15 Sep 2020 03:37:52

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 5'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:43', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-ae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-eae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-ae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-eae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-eae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-eae8-4b66-a00c-58a57c48880c' User entered 'None (0)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:54', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-ae8-4b66-a00c-58a57c48880c' User entered 'No (N)'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-16T00:00:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1aa33d3f-eae8-4b66-a00c-58a57c48880c' User entered '16 Sep 2020 00:00'	System	16 Sep 2020 04:01:16
	System	16 Sep 2020 04:01:16

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 6'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 7'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:39', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:41', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:43', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'None (0)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered 'No (N)'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-09-18T00:59:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '90b838ec-74b3-4b3f-a5e7-cb8854589f75' User entered '18 Sep 2020 00:59'	System	18 Sep 2020 04:59:50
	System	18 Sep 2020 04:59:50

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:01:18

US3742342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:11

US3742342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:11

US3742342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:11

US3742342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:11

US3742342

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:17

US3742342

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	19 Sep 2020 19:12:17

US3742342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:02:12

US3742342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:02:12

US3742342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:02:12

US3742342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:02:12

US3742342

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:02:19

US3742342

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	29 Sep 2020 19:02:19

US3742342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	02 Oct 2020 16:43:45

US3742342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '02 Oct 2020'	Kaitlin Mason (b) (4)	02 Oct 2020 16:43:45

US3742342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	02 Oct 2020 16:43:45

US3742342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	Kaitlin Mason (b) (4)	02 Oct 2020 16:43:45

US3742342

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	02 Oct 2020 16:45:08

US3742342

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	02 Oct 2020 16:45:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:53:10

US3742342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:42:57
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:53:10

US3742342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:53:10

US3742342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'VISIT2'	System	09 Oct 2020 16:53:10

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:09
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '10:35'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '09 Oct 2020 10:35'	System	22 Oct 2020 17:43:09
User entered '9 Oct 2020 10:35'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '098.4' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '078'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'bpm'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'breaths/min'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '140'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'mmHg'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '085'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'mmHg'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:09
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '12:04'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '09 Oct 2020 12:04'	System	22 Oct 2020 17:43:09
User entered '9 Oct 2020 12:04'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '098.6' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '070'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'bpm'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'breaths/min'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '117'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'mmHg'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '070'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'mmHg'	System	09 Oct 2020 17:01:08

US3742342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:58:21

US3742342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:16
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:58:21

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:29
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	09 Oct 2020 16:54:35

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:39
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '11:33'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '09 Oct 2020 11:33'	System	22 Oct 2020 17:43:39
User entered '9 Oct 2020 11:33'	System	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'ONCE'	System	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 15:50:07

US3742342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 09 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 12:21:36
Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 09 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' answered with 'UNSCHEDULED VISIT KIT USED FOR D29 DUE TO SHORTAGE OF KIT A. CONFIRM THAT DAY 29 IS CORRECT' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Nov 2020 15:09:42
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 09 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 11:39:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:54:52

US3742342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:48
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:54:52

US3742342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '10:46'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:54:52

US3742342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '09 Oct 2020 10:46'	System	22 Oct 2020 17:43:48
User entered '9 Oct 2020 10:46'	System	09 Oct 2020 16:54:52

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:33:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 01:57:13
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'UV kit used for Day 29 due to shortage of Kit A' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	30 Oct 2020 13:03:49
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:23:07
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 17:44:01
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '10:40'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered '09 Oct 2020 10:40'	System	22 Oct 2020 17:44:01
User entered '9 Oct 2020 10:40'	System	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered empty.	System	09 Oct 2020 16:55:06

US3742342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:01:14

US3742342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'I'	System	09 Oct 2020 17:01:14

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:07:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'db9e3fe7-1ea3-453d-bc8d-23c5dba78069' User entered 'Yes (Y)'	System	09 Oct 2020 16:07:50
	System	09 Oct 2020 16:07:50

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:07:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'db9e3fe7-1ea3-453d-bc8d-23c5dba78069'	System	09 Oct 2020 16:07:50
User entered '98.6'	System	09 Oct 2020 16:07:50

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:07:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'db9e3fe7-1ea3-453d-bc8d-23c5dba78069'	System	09 Oct 2020 16:07:50
User entered 'No (N)'	System	09 Oct 2020 16:07:50

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:07:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'db9e3fe7-1ea3-453d-bc8d-23c5dba78069'	System	09 Oct 2020 16:07:50
User entered '09 Oct 2020 12:07'	System	09 Oct 2020 16:07:50

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 11:53'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 14:23'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:27', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2cd40a99-da41-48c3-962b-ee31f3331b3a' User entered 'Yes (Y)'	System	10 Oct 2020 13:43:39
	System	10 Oct 2020 13:43:39

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:33', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2cd40a99-da41-48c3-962b-ee31f3331b3a' User entered '97.1'	System	10 Oct 2020 13:43:39
	System	10 Oct 2020 13:43:39

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:35', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2cd40a99-da41-48c3-962b-ee31f3331b3a' User entered 'No (N)'	System	10 Oct 2020 13:43:39
	System	10 Oct 2020 13:43:39

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2cd40a99-da41-48c3-962b-ee31f3331b3a' User entered '10 Oct 2020 09:43'	System	10 Oct 2020 13:43:39
	System	10 Oct 2020 13:43:39

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 15:18'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 2'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca83399a-4f17-4cd5-b374-9e1a3b110afa' User entered 'Yes (Y)'	System	11 Oct 2020 05:03:35
	System	11 Oct 2020 05:03:35

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:27', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca83399a-4f17-4cd5-b374-9e1a3b110afa' User entered '96.3'	System	11 Oct 2020 05:03:35
	System	11 Oct 2020 05:03:35

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:30', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca83399a-4f17-4cd5-b374-9e1a3b110afa' User entered 'No (N)'	System	11 Oct 2020 05:03:35
	System	11 Oct 2020 05:03:35

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:32', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ca83399a-4f17-4cd5-b374-9e1a3b110afa' User entered '11 Oct 2020 01:03'	System	11 Oct 2020 05:03:35
	System	11 Oct 2020 05:03:35

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 3'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:51:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a071e71f-ea9f-4121-9d69-f403a6bb9b26'	System	12 Oct 2020 15:52:01
User entered 'Yes (Y)'	System	12 Oct 2020 15:52:01

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:51:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a071e71f-ea9f-4121-9d69-f403a6bb9b26'	System	12 Oct 2020 15:52:01
User entered '97.6'	System	12 Oct 2020 15:52:01

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:51:57', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a071e71f-ea9f-4121-9d69-f403a6bb9b26'	System	12 Oct 2020 15:52:01
User entered 'No (N)'	System	12 Oct 2020 15:52:01

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:51:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a071e71f-ea9f-4121-9d69-f403a6bb9b26' User entered '12 Oct 2020 11:51'	System	12 Oct 2020 15:52:01
	System	12 Oct 2020 15:52:01

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 4'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '57c66f3f-273e-491e-8ffd-24556a1b4fd7'	System	13 Oct 2020 03:59:27
User entered 'Yes (Y)'	System	13 Oct 2020 03:59:27

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '57c66f3f-273e-491e-8ffd-24556a1b4fd7' User entered '98.3'	System	13 Oct 2020 03:59:27
	System	13 Oct 2020 03:59:27

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:23', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '57c66f3f-273e-491e-8ffd-24556a1b4fd7'	System	13 Oct 2020 03:59:27
User entered 'No (N)'	System	13 Oct 2020 03:59:27

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:24', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '57c66f3f-273e-491e-8ffd-24556a1b4fd7'	System	13 Oct 2020 03:59:27
User entered '12 Oct 2020 23:59'	System	13 Oct 2020 03:59:27

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 5'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:04:43', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f689a186-476d-41b2-89b8-a4a1da9ffe76' User entered 'Yes (Y)'	System	14 Oct 2020 12:04:57
	System	14 Oct 2020 12:04:57

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:04:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f689a186-476d-41b2-89b8-a4a1da9ffe76' User entered '97.8'	System	14 Oct 2020 12:04:57
	System	14 Oct 2020 12:04:57

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:04:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f689a186-476d-41b2-89b8-a4a1da9ffe76'	System	14 Oct 2020 12:04:57
User entered 'No (N)'	System	14 Oct 2020 12:04:57

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:04:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f689a186-476d-41b2-89b8-a4a1da9ffe76' User entered '14 Oct 2020 08:04'	System	14 Oct 2020 12:04:57
	System	14 Oct 2020 12:04:57

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 6'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fef044b7-ba16-4f9a-b245-fdebd7280021' User entered 'Yes (Y)'	System	15 Oct 2020 04:07:10
	System	15 Oct 2020 04:07:10

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:03', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fef044b7-ba16-4f9a-b245-fdebd7280021' User entered '98.1'	System	15 Oct 2020 04:07:10
	System	15 Oct 2020 04:07:10

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:06', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fef044b7-ba16-4f9a-b245-fdebd7280021'	System	15 Oct 2020 04:07:10
User entered 'No (N)'	System	15 Oct 2020 04:07:10

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:07', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fef044b7-ba16-4f9a-b245-fdebd7280021' User entered '15 Oct 2020 00:07'	System	15 Oct 2020 04:07:10
	System	15 Oct 2020 04:07:10

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 7'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fd7169a7-5be6-49ee-b7be-81e4833434b4' User entered 'Yes (Y)'	System	16 Oct 2020 04:00:55
	System	16 Oct 2020 04:00:55

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:50', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fd7169a7-5be6-49ee-b7be-81e4833434b4' User entered '97.6'	System	16 Oct 2020 04:00:55
	System	16 Oct 2020 04:00:55

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fd7169a7-5be6-49ee-b7be-81e4833434b4'	System	16 Oct 2020 04:00:55
User entered 'No (N)'	System	16 Oct 2020 04:00:55

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'fd7169a7-5be6-49ee-b7be-81e4833434b4' User entered '16 Oct 2020 00:00'	System	16 Oct 2020 04:00:55
	System	16 Oct 2020 04:00:55

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:07:56', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a679f95-2098-479a-9ab2-ce5dc97f632e' User entered 'None (1)'	System	09 Oct 2020 16:08:11
	System	09 Oct 2020 16:08:11

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a679f95-2098-479a-9ab2-ce5dc97f632e' User entered 'No (N)'	System	09 Oct 2020 16:08:11
	System	09 Oct 2020 16:08:11

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a679f95-2098-479a-9ab2-ce5dc97f632e' User entered 'No (N)'	System	09 Oct 2020 16:08:11
	System	09 Oct 2020 16:08:11

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:07', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a679f95-2098-479a-9ab2-ce5dc97f632e' User entered 'None (1)'	System	09 Oct 2020 16:08:11
	System	09 Oct 2020 16:08:11

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:09', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a679f95-2098-479a-9ab2-ce5dc97f632e' User entered '09 Oct 2020 12:08'	System	09 Oct 2020 16:08:11
	System	09 Oct 2020 16:08:11

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 11:53'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 14:23'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e59b425-d11d-4292-b27a-74989d05f028'	System	10 Oct 2020 13:43:53
User entered 'None (1)'	System	10 Oct 2020 13:43:53

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e59b425-d11d-4292-b27a-74989d05f028'	System	10 Oct 2020 13:43:53
User entered 'No (N)'	System	10 Oct 2020 13:43:53

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e59b425-d11d-4292-b27a-74989d05f028'	System	10 Oct 2020 13:43:53
User entered 'No (N)'	System	10 Oct 2020 13:43:53

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:50', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e59b425-d11d-4292-b27a-74989d05f028'	System	10 Oct 2020 13:43:53
User entered 'None (1)'	System	10 Oct 2020 13:43:53

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e59b425-d11d-4292-b27a-74989d05f028' User entered '10 Oct 2020 09:43'	System	10 Oct 2020 13:43:53
	System	10 Oct 2020 13:43:53

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 15:18'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 2'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '21b7a4d0-5c5b-45a2-954e-5b12c5ecc6e2'	System	11 Oct 2020 05:03:58
User entered 'None (1)'	System	11 Oct 2020 05:03:58

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:46', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '21b7a4d0-5c5b-45a2-954e-5b12c5ecc6e2' User entered 'No (N)'	System	11 Oct 2020 05:03:58
	System	11 Oct 2020 05:03:58

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:49', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '21b7a4d0-5c5b-45a2-954e-5b12c5ecc6e2' User entered 'No (N)'	System	11 Oct 2020 05:03:58
	System	11 Oct 2020 05:03:58

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '21b7a4d0-5c5b-45a2-954e-5b12c5ecc6e2'	System	11 Oct 2020 05:03:58
User entered 'None (1)'	System	11 Oct 2020 05:03:58

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '21b7a4d0-5c5b-45a2-954e-5b12c5ecc6e2' User entered '11 Oct 2020 01:03'	System	11 Oct 2020 05:03:58
	System	11 Oct 2020 05:03:58

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 3'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:52:14', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2823fc7e-b2f3-4443-8eb5-5460187a471b'	System	12 Oct 2020 15:54:28
User entered 'None (1)'	System	12 Oct 2020 15:54:28

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:52:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2823fc7e-b2f3-4443-8eb5-5460187a471b' User entered 'No (N)'	System	12 Oct 2020 15:54:28
	System	12 Oct 2020 15:54:28

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:52:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2823fc7e-b2f3-4443-8eb5-5460187a471b' User entered 'No (N)'	System	12 Oct 2020 15:54:28
	System	12 Oct 2020 15:54:28

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:23', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2823fc7e-b2f3-4443-8eb5-5460187a471b' User entered 'None (1)'	System	12 Oct 2020 15:54:28
	System	12 Oct 2020 15:54:28

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2823fc7e-b2f3-4443-8eb5-5460187a471b' User entered '12 Oct 2020 11:54'	System	12 Oct 2020 15:54:28
	System	12 Oct 2020 15:54:28

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 4'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:29', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '054f94aa-2c19-46e2-b112-f76d50712964'	System	13 Oct 2020 03:59:41
User entered 'None (1)'	System	13 Oct 2020 03:59:41

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '054f94aa-2c19-46e2-b112-f76d50712964' User entered 'No (N)'	System	13 Oct 2020 03:59:41
	System	13 Oct 2020 03:59:41

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:32', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '054f94aa-2c19-46e2-b112-f76d50712964' User entered 'No (N)'	System	13 Oct 2020 03:59:41
	System	13 Oct 2020 03:59:41

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:34', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '054f94aa-2c19-46e2-b112-f76d50712964' User entered 'None (1)'	System	13 Oct 2020 03:59:41
	System	13 Oct 2020 03:59:41

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:36', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '054f94aa-2c19-46e2-b112-f76d50712964' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 03:59:41
	System	13 Oct 2020 03:59:41

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 5'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:05:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd13d3304-5782-4f84-abd6-48f399f74bd8'	System	14 Oct 2020 12:06:02
User entered 'None (1)'	System	14 Oct 2020 12:06:02

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:05:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd13d3304-5782-4f84-abd6-48f399f74bd8' User entered 'No (N)'	System	14 Oct 2020 12:06:02
	System	14 Oct 2020 12:06:02

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:05:56', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd13d3304-5782-4f84-abd6-48f399f74bd8' User entered 'No (N)'	System	14 Oct 2020 12:06:02
	System	14 Oct 2020 12:06:02

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:05:58', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd13d3304-5782-4f84-abd6-48f399f74bd8' User entered 'None (1)'	System	14 Oct 2020 12:06:02
	System	14 Oct 2020 12:06:02

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd13d3304-5782-4f84-abd6-48f399f74bd8' User entered '14 Oct 2020 08:06'	System	14 Oct 2020 12:06:02
	System	14 Oct 2020 12:06:02

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 6'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:12', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '07927323-4c82-4982-8633-6b463b21d636'	System	15 Oct 2020 04:07:20
User entered 'None (1)'	System	15 Oct 2020 04:07:20

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:13', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '07927323-4c82-4982-8633-6b463b21d636'	System	15 Oct 2020 04:07:20
User entered 'No (N)'	System	15 Oct 2020 04:07:20

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:14', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '07927323-4c82-4982-8633-6b463b21d636'	System	15 Oct 2020 04:07:20
User entered 'No (N)'	System	15 Oct 2020 04:07:20

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:15', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '07927323-4c82-4982-8633-6b463b21d636'	System	15 Oct 2020 04:07:20
User entered 'None (1)'	System	15 Oct 2020 04:07:20

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:18', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '07927323-4c82-4982-8633-6b463b21d636' User entered '15 Oct 2020 00:07'	System	15 Oct 2020 04:07:20
	System	15 Oct 2020 04:07:20

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 7'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:58', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba661210-0916-4ca1-b594-498bc38c6482'	System	16 Oct 2020 04:01:10
User entered 'None (1)'	System	16 Oct 2020 04:01:10

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:00:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba661210-0916-4ca1-b594-498bc38c6482'	System	16 Oct 2020 04:01:10
User entered 'No (N)'	System	16 Oct 2020 04:01:10

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:01', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba661210-0916-4ca1-b594-498bc38c6482' User entered 'No (N)'	System	16 Oct 2020 04:01:10
	System	16 Oct 2020 04:01:10

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba661210-0916-4ca1-b594-498bc38c6482'	System	16 Oct 2020 04:01:10
User entered 'None (1)'	System	16 Oct 2020 04:01:10

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'ba661210-0916-4ca1-b594-498bc38c6482' User entered '16 Oct 2020 00:01'	System	16 Oct 2020 04:01:10
	System	16 Oct 2020 04:01:10

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:17', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:08:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:05', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:08', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:10', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'None (0)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:12', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered 'No (N)'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-09T12:09:14', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8c26e0eb-bcd2-4efc-82fc-51bcf8af1be8' User entered '09 Oct 2020 12:09'	System	09 Oct 2020 16:09:19
	System	09 Oct 2020 16:09:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 11:53'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 14:23'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:43:57', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:44:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:44:58', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:44:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:45:01', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'None (0)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:45:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered 'No (N)'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-10T09:45:06', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '49d41327-5c5a-4ce8-9b33-6f8b301b81c5' User entered '10 Oct 2020 09:45'	System	10 Oct 2020 13:45:11
	System	10 Oct 2020 13:45:11

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '09 Oct 2020 15:18'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 2'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:56', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:03:58', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:05', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:07', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'None (0)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:09', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered 'No (N)'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-11T01:04:11', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '6a2efff8-0ea1-404e-bad0-3e15b95e5ab4' User entered '11 Oct 2020 01:04'	System	11 Oct 2020 05:04:14
	System	11 Oct 2020 05:04:14

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 3'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:44', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:49', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'None (0)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered 'No (N)'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T11:54:58', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af6ab7e-0191-4c86-ab87-20466d60caf0' User entered '12 Oct 2020 11:54'	System	12 Oct 2020 15:55:00
	System	12 Oct 2020 15:55:00

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 4'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:39', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered 'None (0)'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered 'None (0)'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:42', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered 'None (0)'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:47', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823'	System	13 Oct 2020 04:00:03
User entered 'No interference with activity (1)'	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:49', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered 'None (0)'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:51', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered 'None (0)'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:54', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823'	System	13 Oct 2020 04:00:03
User entered 'No (N)'	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-12T23:59:57', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9df9c3f8-8f4d-45e2-987d-307dc671f823' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 04:00:03
	System	13 Oct 2020 04:00:03

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 5'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:14', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124'	System	14 Oct 2020 12:06:51
User entered 'No interference with activity (1)'	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'None (0)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:17', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'None (0)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:19', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'None (0)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:22', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'None (0)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:24', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'None (0)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:29', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered 'No (N)'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-14T08:06:48', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '1af5f3e1-d178-4b88-a98b-05836e77f124' User entered '14 Oct 2020 08:06'	System	14 Oct 2020 12:06:51
	System	14 Oct 2020 12:06:51

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 6'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:27', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:29', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:32', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:33', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'None (0)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:36', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2'	System	15 Oct 2020 04:07:40
User entered 'No (N)'	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-15T00:07:37', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '11b54e4a-0385-413c-8fff-dbd409fb78b2' User entered '15 Oct 2020 00:07'	System	15 Oct 2020 04:07:40
	System	15 Oct 2020 04:07:40

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	09 Oct 2020 15:50:07
User entered 'Day 7'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:08', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:09', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:10', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:11', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:12', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:13', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'None (0)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:14', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered 'No (N)'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-10-16T00:01:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9e14ba51-3449-4a1c-99c1-b53a2b71d56d' User entered '16 Oct 2020 00:01'	System	16 Oct 2020 04:01:19
	System	16 Oct 2020 04:01:19

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 15:50:07

US3742342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:33:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 15:50:07

US3742342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Oct 2020 14:09:02

US3742342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '16 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 14:09:02

US3742342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	20 Oct 2020 14:09:02

US3742342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 14:09:02

US3742342

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Oct 2020 14:09:18

US3742342

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	20 Oct 2020 14:09:18

US3742342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 17:46:52

US3742342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 17:46:52

US3742342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	23 Oct 2020 17:46:52

US3742342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 17:46:52

US3742342

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 17:46:56

US3742342

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	23 Oct 2020 17:46:56

US3742342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Oct 2020 19:16:02

US3742342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '30 Oct 2020'	Hassan Haji (b) (4)	31 Oct 2020 19:16:02

US3742342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	31 Oct 2020 19:16:02

US3742342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	31 Oct 2020 19:16:02

US3742342

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Oct 2020 19:16:34

US3742342

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	31 Oct 2020 19:16:34

US3742342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 18:30:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered 'VISIT3'	System	06 Nov 2020 18:30:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'No (N)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered empty.	System	06 Nov 2020 18:30:10

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05

US3742342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:17

US3742342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 18:30:17

US3742342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:34

US3742342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 18:30:34

US3742342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered '12:06'	Hassan Haji (b) (4)	06 Nov 2020 18:30:34

US3742342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '6 Nov 2020 12:06'	System	06 Nov 2020 18:30:34

US3742342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:45:49
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 18:30:39

US3742342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:05
User entered '1'	System	06 Nov 2020 18:30:39

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 64'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-11T00:33:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '96011ba1-e06a-4ad4-8e22-2c6a4d293833' User entered 'No (N)'	System	11 Nov 2020 05:33:41
	System	11 Nov 2020 05:33:41

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-11T00:33:34', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '96011ba1-e06a-4ad4-8e22-2c6a4d293833'	System	11 Nov 2020 05:33:41
User entered 'No (N)'	System	11 Nov 2020 05:33:41

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-11T00:33:39', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '96011ba1-e06a-4ad4-8e22-2c6a4d293833' User entered '11 Nov 2020 00:33:39'	System	11 Nov 2020 05:33:41
	System	11 Nov 2020 05:33:41

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered 'Day 71'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-18T00:01:35', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a5a583a2-4494-46b9-a12d-4e7a59cc2dfe' User entered 'No (N)'	System	18 Nov 2020 05:01:56
	System	18 Nov 2020 05:01:56

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-18T00:01:40', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a5a583a2-4494-46b9-a12d-4e7a59cc2dfe'	System	18 Nov 2020 05:01:56
User entered 'No (N)'	System	18 Nov 2020 05:01:56

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-18T00:01:43', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a5a583a2-4494-46b9-a12d-4e7a59cc2dfe' User entered '18 Nov 2020 00:01:43'	System	18 Nov 2020 05:01:56
	System	18 Nov 2020 05:01:56

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 21:01:18

US3742342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:44:29
Data entry locked.	System	11 Sep 2020 21:01:18
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 21:01:18

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-24T18:30:19', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '434e3d8e-92d5-4f24-824c-5ee02c897932' User entered 'No (N)'	System	24 Nov 2020 23:30:31
	System	24 Nov 2020 23:30:31

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-24T18:30:23', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '434e3d8e-92d5-4f24-824c-5ee02c897932'	System	24 Nov 2020 23:30:31
User entered 'No (N)'	System	24 Nov 2020 23:30:31

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-24T18:30:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '434e3d8e-92d5-4f24-824c-5ee02c897932' User entered '24 Nov 2020 18:30:25'	System	24 Nov 2020 23:30:31
	System	24 Nov 2020 23:30:31

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-29T00:19:05', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '5cca2a89-a275-4ac6-aad5-aceaaedab24f' User entered 'No (N)'	System	29 Nov 2020 05:19:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-29T00:19:09', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '5cca2a89-a275-4ac6-aad5-aceaaedab24f' User entered 'No (N)'	System	29 Nov 2020 05:19:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-11-29T00:19:11', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '5cca2a89-a275-4ac6-aad5-aceaaedab24f' User entered '29 Nov 2020 00:19:11'	System	29 Nov 2020 05:19:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-09T17:59:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '04a647ba-4513-4fa8-b896-8b700a62e0fa' User entered 'No (N)'	System	09 Dec 2020 22:59:24
	System	09 Dec 2020 22:59:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-09T17:59:18', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '04a647ba-4513-4fa8-b896-8b700a62e0fa' User entered 'No (N)'	System	09 Dec 2020 22:59:24
	System	09 Dec 2020 22:59:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-09T17:59:21', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '04a647ba-4513-4fa8-b896-8b700a62e0fa' User entered '09 Dec 2020 17:59:21'	System	09 Dec 2020 22:59:24
	System	09 Dec 2020 22:59:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-17T11:59:19', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a0176bd-394a-4296-bc1a-5995bf39ca40' User entered 'No (N)'	System	17 Dec 2020 16:59:29
	System	17 Dec 2020 16:59:29

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-17T11:59:23', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a0176bd-394a-4296-bc1a-5995bf39ca40' User entered 'No (N)'	System	17 Dec 2020 16:59:29
	System	17 Dec 2020 16:59:29

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-17T11:59:25', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '2a0176bd-394a-4296-bc1a-5995bf39ca40' User entered '17 Dec 2020 11:59:25'	System	17 Dec 2020 16:59:29
	System	17 Dec 2020 16:59:29

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-20T11:33:28', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e2a4bc76-7094-4591-91d4-41a6a4edadf2' User entered 'No (N)'	System	20 Dec 2020 16:33:37
	System	20 Dec 2020 16:33:37

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-20T11:33:31', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e2a4bc76-7094-4591-91d4-41a6a4edadf2' User entered 'No (N)'	System	20 Dec 2020 16:33:37
	System	20 Dec 2020 16:33:37

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-20T11:33:34', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'e2a4bc76-7094-4591-91d4-41a6a4edadf2' User entered '20 Dec 2020 11:33:34'	System	20 Dec 2020 16:33:37
	System	20 Dec 2020 16:33:37

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-30T19:07:04', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f35cac2b-dcc8-4a08-9a78-68d0c046d353'	System	31 Dec 2020 00:07:14
User entered 'No (N)'	System	31 Dec 2020 00:07:14

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-30T19:07:08', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f35cac2b-dcc8-4a08-9a78-68d0c046d353'	System	31 Dec 2020 00:07:14
User entered 'No (N)'	System	31 Dec 2020 00:07:14

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2020-12-30T19:07:10', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f35cac2b-dcc8-4a08-9a78-68d0c046d353' User entered '30 Dec 2020 19:07:10'	System	31 Dec 2020 00:07:14
	System	31 Dec 2020 00:07:14

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-05T14:04:53', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '94734891-84c9-4abc-836b-6ac8b82300cb' User entered 'No (N)'	System	05 Jan 2021 19:05:12
	System	05 Jan 2021 19:05:12

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-05T14:05:07', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '94734891-84c9-4abc-836b-6ac8b82300cb' User entered 'No (N)'	System	05 Jan 2021 19:05:12

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-05T14:05:10', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '94734891-84c9-4abc-836b-6ac8b82300cb' User entered '05 Jan 2021 14:05:10'	System	05 Jan 2021 19:05:12

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-14T12:03:45', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd3159c5d-83f6-4246-b3f6-5f9d0333008e' User entered 'No (N)'	System	14 Jan 2021 17:04:24
	System	14 Jan 2021 17:04:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-14T12:03:52', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd3159c5d-83f6-4246-b3f6-5f9d0333008e' User entered 'No (N)'	System	14 Jan 2021 17:04:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-14T12:03:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'd3159c5d-83f6-4246-b3f6-5f9d0333008e' User entered '14 Jan 2021 12:03:55'	System	14 Jan 2021 17:04:24
	System	14 Jan 2021 17:04:24

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-24T01:21:59', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f2c36b21-fb4d-4d2c-95bc-5a31f8c94477'	System	24 Jan 2021 06:22:10
User entered 'No (N)'	System	24 Jan 2021 06:22:10

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-24T01:22:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f2c36b21-fb4d-4d2c-95bc-5a31f8c94477'	System	24 Jan 2021 06:22:10
User entered 'No (N)'	System	24 Jan 2021 06:22:10

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-01-24T01:22:03', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'f2c36b21-fb4d-4d2c-95bc-5a31f8c94477' User entered '24 Jan 2021 01:22:03'	System	24 Jan 2021 06:22:10
	System	24 Jan 2021 06:22:10

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-04T12:01:16', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9f64b40c-a1ad-442d-90e8-9f47a615cf61'	System	04 Feb 2021 17:04:45
User entered 'No (N)'	System	04 Feb 2021 17:04:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-04T12:01:17', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9f64b40c-a1ad-442d-90e8-9f47a615cf61'	System	04 Feb 2021 17:04:45
User entered 'No (N)'	System	04 Feb 2021 17:04:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-04T12:01:19', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '9f64b40c-a1ad-442d-90e8-9f47a615cf61' User entered '04 Feb 2021 12:01:19'	System	04 Feb 2021 17:04:45
	System	04 Feb 2021 17:04:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-14T00:07:55', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4ecb7d67-f6a8-4c6f-9037-87f276d26362' User entered 'No (N)'	System	14 Feb 2021 05:08:05
	System	14 Feb 2021 05:08:05

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-14T00:08:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4ecb7d67-f6a8-4c6f-9037-87f276d26362' User entered 'No (N)'	System	14 Feb 2021 05:08:05

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-14T00:08:02', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '4ecb7d67-f6a8-4c6f-9037-87f276d26362' User entered '14 Feb 2021 00:08:02'	System	14 Feb 2021 05:08:05
	System	14 Feb 2021 05:08:05

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-23T12:27:20', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c626beb3-4d64-45fe-940b-90a0e535d8f0'	System	23 Feb 2021 18:52:00
User entered 'No (N)'	System	23 Feb 2021 18:52:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-23T12:27:22', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c626beb3-4d64-45fe-940b-90a0e535d8f0'	System	23 Feb 2021 18:52:00
User entered 'No (N)'	System	23 Feb 2021 18:52:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-02-23T12:27:24', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'c626beb3-4d64-45fe-940b-90a0e535d8f0' User entered '23 Feb 2021 12:27:24'	System	23 Feb 2021 18:52:00
	System	23 Feb 2021 18:52:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-02T13:15:56-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '7eb39cab-5b4b-484b-bdd6-80d23c86c05d'	System	02 Mar 2021 18:20:13
User entered 'No (N)'	System	02 Mar 2021 18:20:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-02T13:16:01-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '7eb39cab-5b4b-484b-bdd6-80d23c86c05d'	System	02 Mar 2021 18:20:13
User entered 'No (N)'	System	02 Mar 2021 18:20:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-02T13:16:03-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '7eb39cab-5b4b-484b-bdd6-80d23c86c05d'	System	02 Mar 2021 18:20:13
User entered '02 Mar 2021 18:16:03'	System	02 Mar 2021 18:20:13

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-07T14:32:41-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '20c67555-bc20-402a-8f9c-f2d67721f466'	System	07 Mar 2021 19:32:48
User entered 'No (N)'	System	07 Mar 2021 19:32:48

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-07T14:32:43-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '20c67555-bc20-402a-8f9c-f2d67721f466'	System	07 Mar 2021 19:32:48
User entered 'No (N)'	System	07 Mar 2021 19:32:48

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-07T14:32:45-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '20c67555-bc20-402a-8f9c-f2d67721f466'	System	07 Mar 2021 19:32:48
User entered '07 Mar 2021 14:32:45'	System	07 Mar 2021 19:32:48

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-17T19:38:42-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'cfd318ee-d890-4fb8-b27c-ae73d779fd78'	System	17 Mar 2021 23:38:51
User entered 'No (N)'	System	17 Mar 2021 23:38:51

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-17T19:38:46-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'cfd318ee-d890-4fb8-b27c-ae73d779fd78'	System	17 Mar 2021 23:38:51
User entered 'No (N)'	System	17 Mar 2021 23:38:51

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-17T19:38:48-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'cfd318ee-d890-4fb8-b27c-ae73d779fd78'	System	17 Mar 2021 23:38:51
User entered '17 Mar 2021 19:38:48'	System	17 Mar 2021 23:38:51

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-21T00:02:17-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '084b287a-462c-4d8b-9fd1-094946e1101d'	System	21 Mar 2021 04:02:55
User entered 'No (N)'	System	21 Mar 2021 04:02:55

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-21T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '084b287a-462c-4d8b-9fd1-094946e1101d'	System	21 Mar 2021 04:02:55
User entered 'No (N)'	System	21 Mar 2021 04:02:55

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-21T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '084b287a-462c-4d8b-9fd1-094946e1101d'	System	21 Mar 2021 04:02:55
User entered '21 Mar 2021 00:02:22'	System	21 Mar 2021 04:02:55

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-28T00:17:52-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0ab18790-76bf-448d-b5d1-8f2567d9dd76'	System	28 Mar 2021 04:18:00
User entered 'No (N)'	System	28 Mar 2021 04:18:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-28T00:17:53-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0ab18790-76bf-448d-b5d1-8f2567d9dd76'	System	28 Mar 2021 04:18:00
User entered 'No (N)'	System	28 Mar 2021 04:18:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-28T00:17:56-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '0ab18790-76bf-448d-b5d1-8f2567d9dd76'	System	28 Mar 2021 04:18:00
User entered '28 Mar 2021 00:17:56'	System	28 Mar 2021 04:18:00

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-04T00:02:29-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8b7d2c06-e4f6-4c52-938c-3f67dabfb48e'	System	04 Apr 2021 04:03:41
User entered 'No (N)'	System	04 Apr 2021 04:03:41

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-04T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8b7d2c06-e4f6-4c52-938c-3f67dabfb48e'	System	04 Apr 2021 04:03:41
User entered 'No (N)'	System	04 Apr 2021 04:03:41

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-04T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '8b7d2c06-e4f6-4c52-938c-3f67dabfb48e' User entered '04 Apr 2021 00:02:33'	System	04 Apr 2021 04:03:41
	System	04 Apr 2021 04:03:41

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-15T11:59:10-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a3c91b57-597e-450d-ba17-8cc3c210f37e' User entered 'No (N)'	System	15 Apr 2021 15:59:20
	System	15 Apr 2021 15:59:20

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-15T11:59:12-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a3c91b57-597e-450d-ba17-8cc3c210f37e'	System	15 Apr 2021 15:59:20
User entered 'No (N)'	System	15 Apr 2021 15:59:20

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-15T11:59:14-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: 'a3c91b57-597e-450d-ba17-8cc3c210f37e' User entered '15 Apr 2021 11:59:14'	System	15 Apr 2021 15:59:20
	System	15 Apr 2021 15:59:20

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-18T00:09:58-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '127692ad-aa1b-4185-aa01-4a28909b8f29'	System	18 Apr 2021 04:10:07
User entered 'No (N)'	System	18 Apr 2021 04:10:07

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-18T00:10:00-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '127692ad-aa1b-4185-aa01-4a28909b8f29' User entered 'No (N)'	System	18 Apr 2021 04:10:07
	System	18 Apr 2021 04:10:07

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-18T00:10:01-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '127692ad-aa1b-4185-aa01-4a28909b8f29' User entered '18 Apr 2021 00:10:01'	System	18 Apr 2021 04:10:07
	System	18 Apr 2021 04:10:07

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-25T00:55:38-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '13753328-845d-4464-b329-2ddcb2afdac5'	System	25 Apr 2021 04:55:45
User entered 'No (N)'	System	25 Apr 2021 04:55:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-25T00:55:40-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '13753328-845d-4464-b329-2ddcb2afdac5'	System	25 Apr 2021 04:55:45
User entered 'No (N)'	System	25 Apr 2021 04:55:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-04-25T00:55:42-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '13753328-845d-4464-b329-2ddcb2afdac5'	System	25 Apr 2021 04:55:45
User entered '25 Apr 2021 00:55:42'	System	25 Apr 2021 04:55:45

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-05-02T14:49:17-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '38f06c33-958e-4eca-bb8a-766809192287'	System	02 May 2021 18:49:39
User entered 'No (N)'	System	02 May 2021 18:49:39

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

Have you been exposed to someone with 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 (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-05-02T14:49:28-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '38f06c33-958e-4eca-bb8a-766809192287'	System	02 May 2021 18:49:39
User entered 'No (N)'	System	02 May 2021 18:49:39

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-05-02T14:49:34-04:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '38f06c33-958e-4eca-bb8a-766809192287'	System	02 May 2021 18:49:39
User entered '02 May 2021 14:49:34'	System	02 May 2021 18:49:39

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:52:04

US3742342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:33:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:52:04
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:52:04

US3742342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:33:36

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 21:10:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-02T13:16:10-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '197bebc-b03fc-4b15-8e32-a81e807c2ec8'	System	02 Mar 2021 18:20:13
User entered 'No (N)'	System	02 Mar 2021 18:20:13

US3742342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:33:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:10:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4CE30D4-BC74-4D71-86B6-6B81398FBDE9)', Time: '2021-03-02T13:16:13-05:00', User OID: 'PatientReportedOutcome (US3742342)', ODM File OID: '197bebc-b03fc-4b15-8e32-a81e807c2ec8' User entered '02 Mar 2021 18:16:13'	System	02 Mar 2021 18:20:13
	System	02 Mar 2021 18:20:13

US3742342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 20:16:42

US3742342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '04 Dec 2020'	Sherry McCammon (b) (4)	04 Dec 2020 20:16:42

US3742342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	04 Dec 2020 20:16:42

US3742342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 20:16:42

US3742342

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 20:16:48

US3742342

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:41:03
User entered 'I'	System	04 Dec 2020 20:16:48

US3742342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Jan 2021 21:31:27

US3742342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '7 Jan 2021'	Hassan Haji (b) (4)	07 Jan 2021 21:31:27

US3742342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	07 Jan 2021 21:31:27

US3742342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	Hassan Haji (b) (4)	07 Jan 2021 21:31:27

US3742342

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Jan 2021 21:31:30

US3742342

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User entered 'I'	System	07 Jan 2021 21:31:30

US3742342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:20

US3742342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:20

US3742342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:20

US3742342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:20

US3742342

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:28

US3742342

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:56:00
User entered '1'	System	10 Feb 2021 14:08:28

US3742342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 16:20:26

US3742342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered '8 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 16:20:26

US3742342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Mar 2021 16:20:26

US3742342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 16:20:26

US3742342

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 16:20:32

US3742342

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User entered '1'	System	10 Mar 2021 16:20:32

US3742342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:21:50

US3742342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:21:50

US3742342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:21:50

US3742342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered 'VISIT4'	System	29 Mar 2021 18:21:50

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'No (N)'	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered empty.	System	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered empty.	System	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered empty.	System	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered empty.	System	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered empty.	System	02 Apr 2021 17:14:11

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19

US3742342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:33:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19

US3742342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:22:05

US3742342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:22:05

US3742342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:23:09

US3742342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:23:09

US3742342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '09:35'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:23:09

US3742342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered '27 Mar 2021 09:35'	System	29 Mar 2021 18:23:09

US3742342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:23:16

US3742342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:03:19
User entered 'I'	System	29 Mar 2021 18:23:16

US3742342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:42

US3742342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:42

US3742342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:42

US3742342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 20:53:42

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:44:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[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 22:18:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:52
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:15:36

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:15:36

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'I'	System	25 Jan 2021 20:55:11

US3742342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:33:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'I'	System	25 Jan 2021 20:55:11

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	25 Jan 2021 21:04:01
DataPoint set to visible.	System	25 Jan 2021 20:55:11

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	25 Jan 2021 21:04:01
DataPoint set to visible.	System	25 Jan 2021 20:55:11

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '09:35'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '21 Jan 2021 09:35'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '087'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'bpm'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '12'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'breaths/min'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '137'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '093'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:33:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	25 Jan 2021 21:04:01
DataPoint set to visible.	System	25 Jan 2021 20:55:11

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '10:20'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '21 Jan 2021 10:20'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '076'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'bpm'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'breaths/min'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '143'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '086'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:04:01

US3742342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'mmHg'	System	25 Jan 2021 21:04:01

US3742342

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:52

US3742342

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:52

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:42

US3742342

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered empty.	System	25 Jan 2021 20:55:42

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4)	25 Jan 2021 21:10:45
	(b) (4), (b) (6)	

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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)	01 May 2021 20:23:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User entered 'mRNA-1273'	System	25 Jan 2021 21:10:45
DataPoint set to visible.	System	25 Jan 2021 20:55:11

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User closed query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 19:12:12
Query 'Per CDMRQ: please review date in IRT and update accordingly' answered with 'according to source documentation, these participants were vaccinated on the documented day and that there is an IRT discrepancy' (Site from DM).	Sherry McCammon (b) (4)	19 Apr 2021 20:05:20
User opened query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:42:08
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 22JAN2021. Please review and reconcile.	(b) (4), (b) (6)	16 Apr 2021 16:42:08
' (Site from DM).		
Query 'Per IRT, Subject had Open Label Day1 Treatment on 22JAN2021. Please review and reconcile.	(b) (4), (b) (6)	09 Apr 2021 14:43:54
' answered with 'Visit conducted on correct listed date.' (Site from DM).		
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 22JAN2021. Please review and reconcile.	(b) (4), (b) (6)	08 Apr 2021 22:16:07
' (Site from DM).		
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '09:47'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User entered '21 Jan 2021 09:47'	System	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User entered 'ONCE'	System	25 Jan 2021 21:10:45

US3742342

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

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:54
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 21:10:45

US3742342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:21

US3742342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:21

US3742342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '09:12'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:21

US3742342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '21 Jan 2021 09:12'	System	25 Jan 2021 20:54:21

US3742342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:33:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:36

US3742342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:36

US3742342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:33:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '09:17'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:36

US3742342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered '21 Jan 2021 09:17'	System	25 Jan 2021 20:54:36

US3742342

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

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:09:18

US3742342

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

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:18:33
User entered 'I'	System	25 Jan 2021 21:09:18

US3742342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Jan 2021 21:57:08

US3742342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered '28 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	28 Jan 2021 21:57:08

US3742342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	28 Jan 2021 21:57:08

US3742342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Jan 2021 21:57:08

US3742342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Jan 2021 21:57:20

US3742342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User entered 'I'	System	28 Jan 2021 21:57:20

US3742342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:30
User entered 'I'	System	28 Jan 2021 21:57:20
DataPoint set to visible.	System	28 Jan 2021 21:57:20

US3742342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:02

US3742342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:02

US3742342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[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 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:02

US3742342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:33:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'OLD29'	System	01 Mar 2021 15:28:02

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01
	(b) (4)	

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '10:26'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered '27 Feb 2021 10:26'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '098.0' F	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '091'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'bpm'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '14'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'breaths/min'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '127'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'mmHg'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '085'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'mmHg'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01
	(b) (4)	

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '11:21'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered '27 Feb 2021 11:21'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '097.5' F	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Other (Other)'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'temporal'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '081'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'bpm'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '16'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'breaths/min'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '124'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'mmHg'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '078'	Sherry McCammon (b) (4)	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:33:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'mmHg'	System	01 Mar 2021 15:33:01

US3742342

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:42

US3742342

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:33:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:42

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Urine (URINE)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Negative (NEGATIVE)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User closed query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' (Site from DM).	(b) (4)	
Query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:30:42
User opened query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 20:31:16
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19
	(b) (4)	

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	03 Mar 2021 14:14:56
	(b) (4)	
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19
	(b) (4)	

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	03 Mar 2021 14:14:56
	(b) (4)	
User entered '10:38'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:19
	(b) (4)	

US3742342

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered empty.	System	03 Mar 2021 14:14:56
User entered '27 Feb 2021 10:38'	System	01 Mar 2021 15:30:19

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'mRNA-1273'	System	01 Mar 2021 15:30:53
DataPoint set to visible.	System	28 Jan 2021 21:57:20

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '27 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '10:50'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered '27 Feb 2021 10:50'	System	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Left Arm (LEFT ARM)'	Sherry McCammon (b) (4)	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'ONCE'	System	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 15:30:53

US3742342

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 15:28:11

US3742342

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:21:01
User entered 'I'	System	01 Mar 2021 15:28:11

US3742342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	19 Mar 2021 21:43:01

US3742342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered '08 Mar 2021'	Kaitlin Mason (b) (4)	19 Mar 2021 21:43:01

US3742342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	19 Mar 2021 21:43:01

US3742342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:33:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered empty.	Kaitlin Mason (b) (4)	19 Mar 2021 21:43:01

US3742342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	19 Mar 2021 21:43:20

US3742342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:33:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:02:42
User entered 'I'	System	19 Mar 2021 21:43:20

US3742342

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:33:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:52:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:44:22

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:56:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:39
User entered	System	20 Sep 2020 17:54:35
'USA-US127-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:54:35

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User closed query 'Per DM CLR: RQ: Response noted, however, DEPRESSION is recorded as a Med History condition. Please review and verify if this is a worsening condition of the Med History. Otherwise, clarify in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Query 'Per DM CLR: RQ: Response noted, however, DEPRESSION is recorded as a Med History condition. Please review and verify if this is a worsening condition of the Med History. Otherwise, clarify in query response.' answered with 'Exacerbation of symptoms' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:38:28
User opened query 'Per DM CLR: RQ: Response noted, however, DEPRESSION is recorded as a Med History condition. Please review and verify if this is a worsening condition of the Med History. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:32:57
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Depression. If yes, please update to reflect the term worsening or exacerbation as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:32:57
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Depression. If yes, please update to reflect the term worsening or exacerbation as appropriate. Otherwise, clarify.' answered with 'NOT WORSENING OF MH CONDITION AS PARTICIPANT DID NOT HAVE SI PRIOR TO EVENT' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 20:16:21
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Depression. If yes, please update to reflect the term worsening or exacerbation as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:10:10
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:12:04
User closed query 'PV Query: Please consider updating event term to final diagnosis of severe episode of recurrent major depressive disorder without psychotic features.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:13:07

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 19:50:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 19:50:25
Data point term sent to Coder	System	09 Oct 2020 19:49:38
Query 'PV Query: Please consider updating event term to final diagnosis of severe episode of recurrent major depressive disorder without psychotic features.' answered with 'EDITED' (Site from Safety).	Kaitlin Mason (b) (4)	09 Oct 2020 19:49:11
DataPoint Un-verified.	Kaitlin Mason (b) (4)	09 Oct 2020 19:49:04
Coding entries removed.	Kaitlin Mason (b) (4)	09 Oct 2020 19:49:04
User entered 'MAJOR DEPRESSIVE DISORDER WITHOUT PSYCHOTIC FEATURES' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Oct 2020 19:49:04
User opened query 'PV Query: Please consider updating event term to final diagnosis of severe episode of recurrent major depressive disorder without psychotic features.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 12:00:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:05:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:05:38
Data point term sent to Coder	System	18 Sep 2020 19:04:41
User entered 'Major depressive disorder'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	01 Oct 2020 14:56:54
	(b) (4), (b) (6)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 19:05:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 19:05:43
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Sep 2020 19:04:20
User entered '18:59'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:05:43
User entered '16 Sep 2020 18:59'	System	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '17 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	01 Oct 2020 14:56:54
	(b) (4), (b) (6)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Sep 2020 19:05:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 19:05:43
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Sep 2020 19:04:20
User entered '18:18'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:05:43
User entered '17 Sep 2020 18:18'	System	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Sep 2020 19:05:43
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Sep 2020 19:04:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Sep 2020 19:05:43
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Sep 2020 19:05:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 19:05:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Sep 2020 19:04:20
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:31
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Subject was hospitalized overnight - admitted to Emergency Department 16SEP2020 at 18:59 and discharged 17SEP2020 at 18:19' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	01 Oct 2020 16:41:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:57:06
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 14:57:04
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:38:41
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '17 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 09:39:39
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'No con meds or proc to add' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 21:03:53
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:33:17
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User closed query 'PV Query: Please confirm if suicidal ideations are considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:13:20
Query 'PV Query: Please confirm if suicidal ideations are considered MH (prior to start of study). If so, please add to MH eCRF.' answered with 'SI was not considered a part of the MH and was thus not added to the eCRF. Subject did not report SI prior to this event' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	09 Oct 2020 19:48:26
User opened query 'PV Query: Please confirm if suicidal ideations are considered MH (prior to start of study). If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 12:00:00
User closed query 'PV Query: Did the subject have a prior medical history of suicidal thoughts?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:58:42
User closed query 'PV Query: How was the reactogenicity after dose 1 and did she have severe events?' (Site from Safety).		02 Oct 2020 12:58:39
User closed query 'PV Query: Were there any triggering factors for the event?' (Site from Safety).		02 Oct 2020 12:58:37
Query 'PV Query: Did the subject have a prior medical history of suicidal thoughts?' answered with 'Per hospital report - subject has a history of depression and has been going to talk therapy for a year. Subject was recently seen by psychiatry and prescribed medication, but the subject has not been able to fill the prescription or start the medication yet. Subject denies history of suicide attempt but did not speak to history of suicidal ideation. ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	01 Oct 2020 16:49:17
Query 'PV Query: How was the reactogenicity after dose 1 and did she have severe events?' answered with 'Diary does not exhibit reactogenicity for solicited symptoms' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	01 Oct 2020 16:44:17

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Were there any triggering factors for the event?' answered with 'Per hospital paperwork, subject has strained relationship with mother and history of depression ' (Site from Safety). DataPoint Verified.	Kaitlin Mason (b) (4) (b) (4)	01 Oct 2020 16:42:37
	(b) (4), (b) (6)	01 Oct 2020 14:56:54
User opened query 'PV Query: Did the subject have a prior medical history of suicidal thoughts?' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:39:33
User opened query 'PV Query: How was the reactogenicity after dose 1 and did she have severe events?' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:37:30
User opened query 'PV Query: Were there any triggering factors for the event?' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:37:01
User entered 'Volunteer was contacted for a day 8 phone call post 1st vaccination on 18Sep2020. When asked about not completing her diary, she reported that she couldn't do it because she was hospitalized due to "some emotional difficulties." Medical Records were requested and received. Per hospital documentation she presented with history of depression with increased thoughts of harming herself on and off for months. Further, the documentation stated that the diagnosis was severe episode of recurrent major depressive disorder, without psychotic features. No medications were taken.'	(b) (4), (b) (6)	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:04:20

US3742342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:33:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 19:04:20

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:33:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:57:42
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:25:04

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LEVORA [ETHINYLESTRADIOL;LEVONORGESTREL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 15:29:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 15:29:51
Data point term sent to Coder	System	12 Sep 2020 15:28:03
User entered 'levora'	Hassan Haji (b) (4)	12 Sep 2020 15:27:05
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'birth control'	Hassan Haji (b) (4)	12 Sep 2020 15:27:05
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'I'	Hassan Haji (b) (4)	12 Sep 2020 15:27:05
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'tablet (TABLET)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'UN May 2019'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 15:27:05

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 14:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:58:48
Data point term sent to Coder	System	01 Oct 2020 14:58:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:03:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:03:20
Data point term sent to Coder	System	29 Sep 2020 18:57:09
User entered 'ZOLOFT'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'DEPRESSION'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:11:16
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 16:52:12
User entered '50' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 16:52:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered '25'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered '19 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 21:14:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 21:14:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 21:14:15
	(b) (4)	
User entered 'UN Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 21:14:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:58:04
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:58:04
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User entered '1'	System	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User entered '1'	System	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:03
User entered '804 (804)'	System	29 Sep 2020 18:56:38

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:27:05
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'out of window - PD raised' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:50:21
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:01:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:47:40
Data point term sent to Coder	System	23 Oct 2020 17:46:05
User entered 'influenza vaccine'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'influenza prophylaxis'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '0.5'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'mL (mL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered '21 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User entered empty.	System	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User entered empty.	System	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:36:45
User entered empty.	System	23 Oct 2020 17:45:52

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: ATOMOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: STRATTERA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 21:18:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:18:55
Data point term sent to Coder	System	25 Jan 2021 21:17:40
User entered 'STRATTERA'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:17:00

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'DEPRESSION'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered '25'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered '14 Jan 2019'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 21:17:00
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:17:00

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:17:00

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 21:17:00

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med ZOLOFT was added/changed on UN OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:55:25
Query 'Per DM CLR: Con Med ZOLOFT was added/changed on UN OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with ' The con med Zoloft that was added is the same dose as the previous Zoloft listed in the con med. same dose and same route and frequency.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 17:19:10
User opened query 'Per DM CLR: Con Med ZOLOFT was added/changed on UN OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:08:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:22:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:22:56
Data point term sent to Coder	System	25 Jan 2021 21:21:43
User entered 'ZOLOFT'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'DEPRESSION'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered '50'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'UN Oct 2020'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:04:16
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 21:20:55
	(b) (4)	

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:20:55

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:20:55

US3742342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:33:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 21:20:55

US3742342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:33:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:38:48
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	12 Mar 2021 20:19:53
	(b) (4)	

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered	System	20 Sep 2020 17:54:35
'USA-US127-2020-MRNA-1273-P301000001'		

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Karen'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Kotloff'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '685 W. Baltimore Street, HSF 480'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Baltimore'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '21201'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered 'US'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
User entered '3'	System	12 Oct 2020 14:13:42
User entered '2'	System	02 Oct 2020 12:58:59
User entered '1'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'USA-US127-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Karen'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Kotloff'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '685 W. Baltimore Street, HSF 480'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Baltimore'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '21201'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered 'US'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
User entered '3'	System	12 Oct 2020 14:13:42
User entered '2'	System	02 Oct 2020 12:58:59
User entered '1'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:33:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered '20/Sep/2020 13:54'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:33:36

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.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'USA-US127-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Karen'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Kotloff'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '685 W. Baltimore Street, HSF 480'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Baltimore'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '21201'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered 'US'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
User entered '3'	System	12 Oct 2020 14:13:42
User entered '2'	System	02 Oct 2020 12:58:59
User entered '1'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:33:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:11:36
User entered '02/Oct/2020 08:58'	System	02 Oct 2020 12:58:59

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:33:36

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.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:11:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:13:30
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:58:59

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered	System	20 Sep 2020 17:54:35
'USA-US127-2020-MRNA-1273-P301000001'		

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Yes (Y)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'No (N)'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Karen'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Kotloff'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '685 W. Baltimore Street, HSF 480'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered 'Baltimore'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:50:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:54:55
User entered '21201'	System	20 Sep 2020 17:54:35

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 14:50:44
User entered 'US'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:33:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
	(b) (4)	
User entered '3'	System	12 Oct 2020 14:13:42
User entered '2'	System	02 Oct 2020 12:58:59
User entered '1'	System	20 Sep 2020 17:55:00

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:33:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:11:36
User entered '12/Oct/2020 14:13'	System	12 Oct 2020 14:13:42

US3742342

Folder: SAE USA-US127-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:33:36

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.	Karen Kotloff (b) (4)	23 Feb 2021 18:05:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:11:36
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:13:42