

US3262133 (Prod: AB Clinical Trials - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:17:39

All time stamps listed in this document are displayed in GMT

US3262133

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Participant ID

US3262133

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

US3262133

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

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

Visit date (dd MMM yyyy)	07 AUG 2020
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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	SCRN
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US3262133

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	58
Age Units	YEARS
Age (Derived)	58
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3262133

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input 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

US3262133

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3262133

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Were any significant conditions reported?

Yes ☒

No ☐

US3262133

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	GASTRIC ESOPHAGEAL REFLEX DISEASE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
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 DEC 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	DEC 2002
Stop Year (derived)	2002

US3262133

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	INTERMITTENT COLITIS
Start date (dd MMM yyyy)	UN JUL 2012
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)	JUL 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Condition	ALLERGY TO FOOD (SHELLFISH)
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3262133

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:05
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	172 lb
BMI (<i>xxx.x</i>)	31.52499 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262133

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

US3262133

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*) 7 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 2002

Date of surgery unknown False

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

Date of last menstruation unknown False

US3262133

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3262133

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

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	

US3262133

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143359

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 ☒

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Height	ND - Not Done
Weight	ND - Not Done

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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)	7 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 15:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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)	7 AUG 2020
Time of assessment (00:00-23:59)	15:59 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 15:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3262133

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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.

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 15:29 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 15:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3262133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 AUG 2020
Collection time (00:00-23:59)	15:20 (24 HR)
Collection date and time (derived)	7 AUG 2020 15:20

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:10	7 AUG 2020 15:10
Nasopharyngeal Swab 2	No		

US3262133

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

98.1 °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

07 AUG 2020 16:06

PC Open Date & Time

07 AUG 2020 15:49

PC Close Date & Time

07 AUG 2020 18:19

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	07 AUG 2020 20:40
PC Open Date & Time	07 AUG 2020 19:14
PC Close Date & Time	08 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 AUG 2020 14:40

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 14:52

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

10 AUG 2020 20:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 AUG 2020 17:42

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:12

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:56

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

07 AUG 2020 16:07

PC Open Date & Time

07 AUG 2020 15:49

PC Close Date & Time

07 AUG 2020 18:19

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

07 AUG 2020 20:41

PC Open Date & Time

07 AUG 2020 19:14

PC Close Date & Time

08 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

08 AUG 2020 14:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

09 AUG 2020 14:53

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

10 AUG 2020 20:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

11 AUG 2020 17:42

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

12 AUG 2020 20:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

13 AUG 2020 19:57

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 16:08
PC Open Date & Time	07 AUG 2020 15:49
PC Close Date & Time	07 AUG 2020 18:19

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 20:42
PC Open Date & Time	07 AUG 2020 19:14
PC Close Date & Time	08 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 14:53
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

54 of 2178

EAB) (1725)

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 20:05
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:43
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:13
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:57
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 14 AUG 2020 19:31

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 19:31
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3262133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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)	05 SEP 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	05 SEP 2020 10:35
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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)	05 SEP 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	05 SEP 2020 11:45
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3262133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 SEP 2020

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

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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) 05 SEP 2020

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 05 SEP 2020 11:15

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

US3262133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 SEP 2020

Collection time (00:00-23:59)

10:39 (24 HR)

Collection date and time (derived)

05 SEP 2020 10:39

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)			05 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:37	05 SEP 2020 10:37
Nasopharyngeal Swab 2	No		

US3262133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 11:56

PC Open Date & Time

05 SEP 2020 11:35

PC Close Date & Time

05 SEP 2020 14:05

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	05 SEP 2020 18:55
PC Open Date & Time	05 SEP 2020 15:00
PC Close Date & Time	06 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

101.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 13:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

08 SEP 2020 20:15

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:46

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

05 SEP 2020 11:56

PC Open Date & Time

05 SEP 2020 11:35

PC Close Date & Time

05 SEP 2020 14:05

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

05 SEP 2020 18:55

PC Open Date & Time

05 SEP 2020 15:00

PC Close Date & Time

06 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

06 SEP 2020 13:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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 ☐

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

70

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:07

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

08 SEP 2020 20:16

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

09 SEP 2020 18:59

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

11 SEP 2020 17:47

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 11:57
PC Open Date & Time	05 SEP 2020 11:35
PC Close Date & Time	05 SEP 2020 14:05

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 18:56
PC Open Date & Time	05 SEP 2020 15:00
PC Close Date & Time	06 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

		Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 13:17	
PC Open Date & Time	06 SEP 2020 12:00	
PC Close Date & Time	07 SEP 2020 11:59	

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

100 of 2178

EAB) (1725)

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:07
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

102 of 2178

EAB) (1725)

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:16
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

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
EAB) (1725)

104 of 2178

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:59
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

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 ☒

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 17:47
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3262133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:15

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	07:55 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 07:55
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

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.

US3262133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	08:03 (24 HR)
Collection date and time (derived)	07 OCT 2020 08:03

US3262133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:30:16

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 OCT 2020 08:08:22
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 14 OCT 2020 21:20:21

Patient Cloud Open Date & Time 14 OCT 2020 00:01

Patient Cloud Close Date & Time 18 OCT 2020 23:59

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 21:11:11

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 22:11:22

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 NOV 2020 14:50:47
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 23:26:16

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 20:22:43

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

23 DEC 2020 17:55:05

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	31 DEC 2020 23:59
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US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 JAN 2021 19:20:08
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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	18 JAN 2021 18:38:59
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 12:28:36

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

02 FEB 2021 19:54:59

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

03 MAR 2021 21:47:05

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 MAR 2021 16:15:09
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

22 MAR 2021 12:17:54

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 <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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 19:16:56

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 12:50:50

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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="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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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="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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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°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 ☐

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:17:39

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		03 MAR 2021 21:47:16

US3262133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:40:19

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:40:19

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262133

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 12:06
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

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.

US3262133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	22 MAR 2021 12:15

US3262133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3262133

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:17:39

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"/>

US3262133

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:17:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3262133

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

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

Visit date (dd MMM yyyy)	28 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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US3262133

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Date of updated informed consent (dd MMM yyyy) 28 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3262133

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

10:24 (24 HR)

Collection date and time (derived)

28 JAN 2021 10:24

US3262133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	10:22
Collection Date and Time (derived)	28 JAN 2021 10:22

US3262133

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 20:08:56

Generated On: 09 Jun 2021 16:17:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

AEID	
Adverse event	SINUS INFECTION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

AEID

Adverse event

ANAPHYLAXIS UNKNOWN

CAUSE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

339 of 2178

EAB) (1725)

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

AEID	USA-US069-2021-MRNA-1273-P30 1000003
Adverse event	EPIGASTRIC PAIN DUE TO RECURRENT BILIARY COLIC
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)	08 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	10 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	341 of 2178

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	CHOLECYSTECTOMY
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

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

1 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

343 of 2178

EAB) (1725)

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Apr 2021 19:13:04

Generated On: 09 Jun 2021 16:17:39

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

Yes ☒

No ☐

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

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	ALLEGRA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	180
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	LANSOPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GASTRIC ESOPHAGEAL REFLUX DISEASE
Dose per administration	30
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	CITOPROLAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	FAMOTIDINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GASTRIC ESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN JAN 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	AMLODIPINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

	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 JAN 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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	CEFDINIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SINUS INFECTION
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

	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)		29 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	EPINEPHRINE AUTO-INJECTOR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANAPHYLAXIS REACTION
Dose per administration	0.3
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		7 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		7 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	CITALOPRAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

	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 JAN 2021
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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	MACROBID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	URINARY TRACT INFECTION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	URINARY TRACT INFECTION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

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)	15 FEB 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 FEB 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	BREO ELLIPTA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	100/25
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

	Respiratory (Inhalation)	<input checked="" 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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
<hr/>		
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"/>	

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	ADVAIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	250/50
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

	Respiratory (Inhalation)	<input checked="" 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)	UN JAN 2021	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	ALEVE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN AT INJECTION SITE
Dose per administration	440
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

	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)		08 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

Name of Medication	ALEVE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FEVER AND PAIN AT INJECTION SITE, HEADACHE
Dose per administration	440
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2178

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 07 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input 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"/>

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 MAR 2021	ROBOT XI ASSISTED CHOLECYSTECTOMY	Adverse Event	

US3262133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:17:39

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

US3262133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:17:39

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 ☐

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

SAEID	USA-US069-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

SAEID	USA-US069-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/MAR/2021 12:58
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

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

SAEID	USA-US069-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 09:43
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

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

SAEID	USA-US069-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 08:35
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

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 16:34:25

Generated On: 09 Jun 2021 16:17:39

SAEID	USA-US069-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 09:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3262133 (Prod: AB Clinical Trials - Hunt - PPDS)

US3262133

Form: Participant Creation

Generated On: 09 Jun 2021 16:17:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'US3262133'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 22:29:06

US3262133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:05:27

US3262133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 22:29:07

US3262133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Clinic (Clinic)'	Alia Bober (b) (4)	08 Aug 2020 19:05:27
	(b) (4)	

US3262133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'SCRN'	System	08 Aug 2020 19:05:27

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 22:29:08

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '58'	Alia Bober (b) (4) [REDACTED]	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'YEARS'	System	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '58'	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Female (F)'	Alia Bober (b) (4) [REDACTED]	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'I'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:05:49
	(b) (4)	

US3262133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:17:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:05:49

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '07 Aug 2020'	Daisy Langarica (b) (4)	07 Aug 2020 23:04:15
	(b) (4)	

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Aug 2020'	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2020'	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	07 Aug 2020 23:04:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 23:04:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 23:04:20
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	07 Aug 2020 23:04:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 23:04:15
User entered empty.	Daisy Langarica (b) (4)	07 Aug 2020 23:04:15
	(b) (4)	

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	07 Aug 2020 23:04:15
	(b) (4)	

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Daisy Langarica (b) (4) (b) (4)	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	07 Aug 2020 23:04:15
	(b) (4)	

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 22:29:07

US3262133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:17:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '1'	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	07 Aug 2020 23:03:58
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:17:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:06:05
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:29:34
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:34:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 19:08:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 19:08:53
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 19:07:42
User entered 'Type II Diabetes'	Alia Bober (b) (4)	08 Aug 2020 19:06:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'UN Jan 2019'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:06:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:06:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:06:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2019'	System	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2019'	System	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:06:44

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:08:00
Query 'Per DM CLR: Please note that there is no Con Alia Bober Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con med recorded.' (Site from DM).	(b) (4)	06 Oct 2020 14:18:52
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:34:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:08:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:08:54
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 19:07:42
User entered 'Asthma'	Alia Bober (b) (4)	08 Aug 2020 19:07:09
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'UN UNK 1990'	Alia Bober (b) (4)	08 Aug 2020 19:07:09
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:07:09
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:07:09
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:07:09

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:07:09
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 1990'	System	08 Aug 2020 19:07:09

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '1990'	System	08 Aug 2020 19:07:09

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:07:09

US3262133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:07:09

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:09:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:09:54
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 19:08:45
User entered 'Depression'	Alia Bober (b) (4)	08 Aug 2020 19:07:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'UN UNK 2002'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:07:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	08 Aug 2020 19:07:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:07:44
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2002'	System	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2002'	System	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:07:44

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:08:52
Query 'Per DM CLR: Please note that there is no Con Alia Bober Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con med recorded.' (Site from DM).	(b) (4)	06 Oct 2020 14:19:00
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:34:59
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:09:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 19:09:53
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 19:08:43
User entered 'Hypertension'	Alia Bober (b) (4)	08 Aug 2020 19:08:29
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'UN UNK 2015'	Alia Bober (b) (4)	08 Aug 2020 19:08:29
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:08:29
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:08:29
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2015'	System	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2015'	System	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:08:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:15:15
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:15:15
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 19:10:46
User entered 'Gastric Esophageal Reflex Disease'	Alia Bober (b) (4)	08 Aug 2020 19:10:29
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'UN UNK 2001'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2001'	System	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2001'	System	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	08 Aug 2020 19:10:29

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
Query 'Per DM CLR- Requery: Response noted, however, please confirm what has been updated as there is still no recorded associated condition/diagnosis in the MedHistory eCRF as to why the procedure was done. Update as appropriate, otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:51:12
User opened query 'Per DM CLR- Requery: Response noted, however, please confirm what has been updated as there is still no recorded associated condition/diagnosis in the MedHistory eCRF as to why the procedure was done. Update as appropriate, otherwise clarify.' (Site from DM).		10 Oct 2020 07:12:58
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		10 Oct 2020 07:12:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Updated.' (Site from DM).	Alia Bober (b) (4)	06 Oct 2020 14:19:36
	(b) (4)	
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:35:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:40
	(b) (4)	

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:12:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:12:54
Data point term sent to Coder	System	08 Aug 2020 19:11:47
User entered 'Complete Hysterectomy'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'UN UNK 2002'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'UN Dec 2002'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2002'	System	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2002'	System	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Dec 2002'	System	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2002'	System	08 Aug 2020 19:11:21

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 23:57:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 23:57:37
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 00:34:35
User entered 'Intermittent Colitis'	(b) (4), (b) (6)	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'un Jul 2012'	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) [REDACTED]	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jul 2012'	System	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2012'	System	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	12 Nov 2020 00:34:06

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 13:16:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 13:16:46
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 00:41:37
User entered 'Allergy to food (shellfish)'	(b) (4), (b) (6)	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'un UNK 2008'	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'Jan 2008'	System	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '2008'	System	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered empty.	System	12 Nov 2020 00:40:41

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '07 Aug 2020'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '15:05'	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered '07 Aug 2020 15:05'	System	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '62' in	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	
DataPoint set to visible.	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '172' lb	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	
DataPoint set to visible.	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
Amendment Manager: User entered '31.52499'	System	16 Sep 2020 23:48:26
User entered '31.5'	System	08 Aug 2020 19:12:16
DataPoint set to visible.	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'kg/m2'	System	08 Aug 2020 19:12:16
DataPoint set to visible.	System	07 Aug 2020 23:04:15

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' (Site from DM). Query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' answered with 'removed per query ' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 10:10:17
User opened query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' (Site from DM). User closed query 'Per CDM: Per CCGs pages 15-16 ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' answered with 'Recorded at screening.' (Site from DM).	Daisy Langarica (b) (4)	18 Nov 2020 21:55:37
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	Daisy Langarica (b) (4)	18 Nov 2020 21:55:26
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:17:33
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:17:33
User entered '98.3' F	Alia Bober (b) (4)	28 Sep 2020 03:35:32
	(b) (4)	15 Sep 2020 18:49:54
	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4) (b) (4)	18 Nov 2020 21:55:26
User entered 'Oral (Oral)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	18 Nov 2020 21:55:26
	(b) (4)	
User entered '79'	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'bpm'	System	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	18 Nov 2020 21:55:26
	(b) (4)	
User entered '12'	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'breaths/min'	System	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	18 Nov 2020 21:55:26
	(b) (4)	
User entered '129'	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'mmHg'	System	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	18 Nov 2020 21:55:26
	(b) (4)	
User entered '82'	Alia Bober (b) (4)	08 Aug 2020 19:12:16
	(b) (4)	

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User entered 'mmHg'	System	08 Aug 2020 19:12:16

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51

US3262133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51

US3262133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:12:36

US3262133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:57:07
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		05 Sep 2020 18:31:05
User entered '7 Aug 2020'	Alia Bober (b) (4)	08 Aug 2020 19:12:36
	(b) (4)	

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '7 Aug 2020'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:13:38

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:13:38
	(b) (4)	

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	30 Oct 2020 15:07:22
Comment added 'COMPLETE HYSTERECTOMY'.	Alia Bober (b) (4)	31 Aug 2020 14:57:36
	(b) (4)	
User opened query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	08 Aug 2020 19:13:38
User entered 'Surgically sterile (SURGICALLY STERILE)'	Alia Bober (b) (4)	08 Aug 2020 19:13:38
	(b) (4)	

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	30 Oct 2020 15:07:22
User entered 'n/a' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	31 Aug 2020 14:59:45
User entered 'Complete Hysterectomy'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:13:38

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'UN UNK 2002' reason for change:	Alia Bober (b) (4)	31 Aug 2020 14:59:45
Data Entry Error	(b) (4)	
User entered empty.	Alia Bober (b) (4)	08 Aug 2020 19:13:38
	(b) (4)	

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Per DM CLR: Date of surgery unknown = Yes. However, UNK 2002 is recorded as start date of COMPLETE HYSTERECTOMY. Please review and reconcile as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:27:30
Query 'Per DM CLR: Date of surgery unknown = Yes. However, UNK 2002 is recorded as start date of COMPLETE HYSTERECTOMY. Please review and reconcile as appropriate. Otherwise, clarify in query response.	Alia Bober (b) (4)	31 Aug 2020 15:00:15
' answered with 'Date entered.' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Alia Bober (b) (4)	31 Aug 2020 14:59:45
User opened query 'Per DM CLR: Date of surgery unknown = Yes. However, UNK 2002 is recorded as start date of COMPLETE HYSTERECTOMY. Please review and reconcile as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 04:24:01
User entered '1'	Alia Bober (b) (4)	08 Aug 2020 19:13:38
	(b) (4)	

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:13:38

US3262133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:17:39

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:13:38

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:14:53

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[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) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:14:53

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:14:53

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User closed query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	08 Aug 2020 19:15:00
User entered '1' reason for change: Data Entry Error	Alia Bober (b) (4)	08 Aug 2020 19:15:00
	(b) (4)	
User opened query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	08 Aug 2020 19:14:53
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered '0'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:14:53

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	08 Aug 2020 19:14:53
	(b) (4)	

US3262133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:17:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 06:33:51
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:30:16
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:14:53

US3262133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:07

US3262133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '7 Aug 2020'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:07

US3262133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Clinic (Clinic)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:07

US3262133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'VISIT1'	System	08 Aug 2020 19:16:07

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 22:29:10

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:02:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:02:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 22:29:10
User entered '143359' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 22:29:10

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 22:29:10

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	Alia Bober (b) (4)	08 Aug 2020 19:16:32

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	Alia Bober (b) (4)	08 Aug 2020 19:16:32

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:32

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:32

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:16:32

US3262133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) Alia Bober (b) (4)	28 Sep 2020 03:35:19
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:03:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:33:01

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:31:59
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:36:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:35:58
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:02:32
User entered '62' in	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 03:35:58
User entered '172' lb	Alia Bober (b) (4)	08 Aug 2020 19:17:51
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:31:59
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:36:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:35:58
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:02:32
User entered '62' in	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 03:35:58
User entered '172' lb	Alia Bober (b) (4)	08 Aug 2020 19:17:51
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Pre-Dose (PREDOSE)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '7 Aug 2020'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '15:05'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '7 Aug 2020 15:05'	System	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '98.3' F	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Oral (Oral)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '79'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'bpm'	System	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '12'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'breaths/min'	System	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '129'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '82'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:31:59
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:36:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	28 Sep 2020 03:35:58
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:02:32
User entered '62' in	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:17:51

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:17:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 03:35:58
User entered '172' lb	Alia Bober (b) (4)	08 Aug 2020 19:17:51
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Post-Dose (POSTDOSE)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '7 Aug 2020'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'value correct' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:22:45
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 23:06:32
User entered '15:59'	Alia Bober (b) (4)	08 Aug 2020 19:18:35
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '7 Aug 2020 15:59'	System	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '98.1' F	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Oral (Oral)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '83'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'bpm'	System	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '16'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'breaths/min'	System	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '128'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '88'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	08 Aug 2020 19:18:35

US3262133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
Comment added 'Done at screening.'	(b) (4) Alia Bober (b) (4)	08 Aug 2020 19:19:27
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:19:13

US3262133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Alia Bober (b) (4)	08 Aug 2020 19:19:13
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	07 Aug 2020 23:04:54
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07 Aug 2020'	(b) (4) Daisy Langerica (b) (4)	07 Aug 2020 23:04:54
	(b) (4)	

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '15:29'	(b) (4) Daisy Langarica (b) (4)	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '07 Aug 2020 15:29'	System	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langerica (b) (4) (b) (4)	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'ONCE'	System	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 23:04:54

US3262133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:13

US3262133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '7 Aug 2020'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:13

US3262133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '15:20'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:13

US3262133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '7 Aug 2020 15:20'	System	08 Aug 2020 19:20:13

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4) System	08 Aug 2020 19:20:37
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Aug 2020 19:20:37
User entered '7 Aug 2020' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:37
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	08 Aug 2020 19:20:26
User entered empty.	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '15:10'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '7 Aug 2020 15:10'	System	08 Aug 2020 19:20:37
User entered empty.	System	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered empty.	System	08 Aug 2020 19:20:26

US3262133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	08 Aug 2020 19:19:37

US3262133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	08 Aug 2020 19:19:37

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:06:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0824006a-5bc0-4097-9f85-f9fc9721d1a3' User entered 'Yes (Y)'	System	07 Aug 2020 23:06:39
	System	07 Aug 2020 23:06:39

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:06:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0824006a-5bc0-4097-9f85-f9fc9721d1a3' User entered '98.1'	System	07 Aug 2020 23:06:39
	System	07 Aug 2020 23:06:39

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:06:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0824006a-5bc0-4097-9f85-f9fc9721d1a3'	System	07 Aug 2020 23:06:39
User entered 'No (N)'	System	07 Aug 2020 23:06:39

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:06:35', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0824006a-5bc0-4097-9f85-f9fc9721d1a3' User entered '07 Aug 2020 16:06'	System	07 Aug 2020 23:06:39
	System	07 Aug 2020 23:06:39

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 15:49'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 18:19'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17afc698-4289-4133-8356-286f9f63a1e8' User entered 'Yes (Y)'	System	08 Aug 2020 03:40:50
	System	08 Aug 2020 03:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17afc698-4289-4133-8356-286f9f63a1e8' User entered '98.3'	System	08 Aug 2020 03:40:50
	System	08 Aug 2020 03:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17afc698-4289-4133-8356-286f9f63a1e8'	System	08 Aug 2020 03:40:50
User entered 'No (N)'	System	08 Aug 2020 03:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17afc698-4289-4133-8356-286f9f63a1e8'	System	08 Aug 2020 03:40:50
User entered '07 Aug 2020 20:40'	System	08 Aug 2020 03:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 19:14'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 2'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:39:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered 'Yes (Y)'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:40:25', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered '97.8'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:40:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered 'Yes (Y)'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).		30 Mar 2021 09:30:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:40:41', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered '1'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:40:41', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered '0'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:40:49', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3a85f398-b26b-464b-bb14-70793043e63b' User entered '08 Aug 2020 14:40'	System	08 Aug 2020 21:40:50
	System	08 Aug 2020 21:40:50

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 3'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '15725f41-d15b-4add-aaa7-66bac8aefffd' User entered 'Yes (Y)'	System	09 Aug 2020 21:52:20
	System	09 Aug 2020 21:52:20

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '15725f41-d15b-4add-aaa7-66bac8aefffd' User entered '98.5'	System	09 Aug 2020 21:52:20
	System	09 Aug 2020 21:52:20

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:13', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '15725f41-d15b-4add-aaa7-66bac8aefffd' User entered 'No (N)'	System	09 Aug 2020 21:52:20
	System	09 Aug 2020 21:52:20

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '15725f41-d15b-4add-aaa7-66bac8aefffd' User entered '09 Aug 2020 14:52'	System	09 Aug 2020 21:52:20
	System	09 Aug 2020 21:52:20

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 4'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:13', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17aa9831-c32c-4daf-b3a8-4c3f7e282f09'	System	11 Aug 2020 03:04:32
User entered 'Yes (Y)'	System	11 Aug 2020 03:04:32

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17aa9831-c32c-4daf-b3a8-4c3f7e282f09' User entered '98.3'	System	11 Aug 2020 03:04:32
	System	11 Aug 2020 03:04:32

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17aa9831-c32c-4daf-b3a8-4c3f7e282f09'	System	11 Aug 2020 03:04:32
User entered 'No (N)'	System	11 Aug 2020 03:04:32

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:31', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '17aa9831-c32c-4daf-b3a8-4c3f7e282f09'	System	11 Aug 2020 03:04:32
User entered '10 Aug 2020 20:04'	System	11 Aug 2020 03:04:32

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 5'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:17', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0ef436b9-338d-4fb0-bc87-91d5353d6f60' User entered 'Yes (Y)'	System	12 Aug 2020 00:42:37
	System	12 Aug 2020 00:42:37

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0ef436b9-338d-4fb0-bc87-91d5353d6f60' User entered '98.3'	System	12 Aug 2020 00:42:37
	System	12 Aug 2020 00:42:37

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:27', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0ef436b9-338d-4fb0-bc87-91d5353d6f60'	System	12 Aug 2020 00:42:37
User entered 'No (N)'	System	12 Aug 2020 00:42:37

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:33', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0ef436b9-338d-4fb0-bc87-91d5353d6f60'	System	12 Aug 2020 00:42:37
User entered '11 Aug 2020 17:42'	System	12 Aug 2020 00:42:37

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 6'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:12:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '8c31fdf7-b537-4f96-8e61-779204d49b0d' User entered 'Yes (Y)'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:12:35', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '8c31fdf7-b537-4f96-8e61-779204d49b0d' User entered '98.5'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:12:51', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '8c31fdf7-b537-4f96-8e61-779204d49b0d'	System	13 Aug 2020 03:13:01
User entered 'No (N)'	System	13 Aug 2020 03:13:01

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:12:57', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '8c31fdf7-b537-4f96-8e61-779204d49b0d' User entered '12 Aug 2020 20:12'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 7'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:40', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a1c3ae1e-ed9e-4baf-98dd-e9a2ea3e0c41' User entered 'Yes (Y)'	System	14 Aug 2020 02:56:56
	System	14 Aug 2020 02:56:56

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:45', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a1c3ae1e-ed9e-4baf-98dd-e9a2ea3e0c41' User entered '97.9'	System	14 Aug 2020 02:56:56
	System	14 Aug 2020 02:56:56

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a1c3ae1e-ed9e-4baf-98dd-e9a2ea3e0c41'	System	14 Aug 2020 02:56:56
User entered 'No (N)'	System	14 Aug 2020 02:56:56

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a1c3ae1e-ed9e-4baf-98dd-e9a2ea3e0c41'	System	14 Aug 2020 02:56:56
User entered '13 Aug 2020 19:56'	System	14 Aug 2020 02:56:56

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4e8f484e-ee97-47dc-be68-35791ece036a' User entered 'None (1)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:37', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4e8f484e-ee97-47dc-be68-35791ece036a'	System	07 Aug 2020 23:07:53
User entered 'No (N)'	System	07 Aug 2020 23:07:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:42', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4e8f484e-ee97-47dc-be68-35791ece036a' User entered 'No (N)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:45', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4e8f484e-ee97-47dc-be68-35791ece036a' User entered 'None (1)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:50', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4e8f484e-ee97-47dc-be68-35791ece036a' User entered '07 Aug 2020 16:07'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 15:49'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 18:19'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14813a5f-cc30-4e0a-a05b-3796a36da449'	System	08 Aug 2020 03:41:16
User entered 'None (1)'	System	08 Aug 2020 03:41:16

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:40:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14813a5f-cc30-4e0a-a05b-3796a36da449' User entered 'No (N)'	System	08 Aug 2020 03:41:16
	System	08 Aug 2020 03:41:16

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:41:03', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14813a5f-cc30-4e0a-a05b-3796a36da449'	System	08 Aug 2020 03:41:16
User entered 'No (N)'	System	08 Aug 2020 03:41:16

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:41:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14813a5f-cc30-4e0a-a05b-3796a36da449'	System	08 Aug 2020 03:41:16
User entered 'None (1)'	System	08 Aug 2020 03:41:16

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:41:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14813a5f-cc30-4e0a-a05b-3796a36da449' User entered '07 Aug 2020 20:41'	System	08 Aug 2020 03:41:16
	System	08 Aug 2020 03:41:16

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 19:14'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 2'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1ac12210-d81a-429e-a9a7-642b9b980fbd' User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	08 Aug 2020 21:41:34

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1ac12210-d81a-429e-a9a7-642b9b980fbd' User entered 'No (N)'	System	08 Aug 2020 21:41:34
	System	08 Aug 2020 21:41:34

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:17', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1ac12210-d81a-429e-a9a7-642b9b980fbd' User entered 'No (N)'	System	08 Aug 2020 21:41:34
	System	08 Aug 2020 21:41:34

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1ac12210-d81a-429e-a9a7-642b9b980fbd' User entered 'None (1)'	System	08 Aug 2020 21:41:34
	System	08 Aug 2020 21:41:34

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1ac12210-d81a-429e-a9a7-642b9b980fbd' User entered '08 Aug 2020 14:41'	System	08 Aug 2020 21:41:34
	System	08 Aug 2020 21:41:34

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 3'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:45', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f5977f78-a18e-490b-8ad3-05fbb8c65737'	System	09 Aug 2020 21:53:02
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 21:53:02

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f5977f78-a18e-490b-8ad3-05fbb8c65737'	System	09 Aug 2020 21:53:02
User entered 'No (N)'	System	09 Aug 2020 21:53:02

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:49', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f5977f78-a18e-490b-8ad3-05fbb8c65737' User entered 'No (N)'	System	09 Aug 2020 21:53:02
	System	09 Aug 2020 21:53:02

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:52:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f5977f78-a18e-490b-8ad3-05fbb8c65737' User entered 'None (1)'	System	09 Aug 2020 21:53:02
	System	09 Aug 2020 21:53:02

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f5977f78-a18e-490b-8ad3-05fbb8c65737' User entered '09 Aug 2020 14:53'	System	09 Aug 2020 21:53:02
	System	09 Aug 2020 21:53:02

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 4'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:35', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5599f9d5-f33b-4b1e-84be-c01981dc205b' User entered 'None (1)'	System	11 Aug 2020 03:04:50
	System	11 Aug 2020 03:04:50

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5599f9d5-f33b-4b1e-84be-c01981dc205b' User entered 'No (N)'	System	11 Aug 2020 03:04:50
	System	11 Aug 2020 03:04:50

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:42', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5599f9d5-f33b-4b1e-84be-c01981dc205b' User entered 'No (N)'	System	11 Aug 2020 03:04:50
	System	11 Aug 2020 03:04:50

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:44', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5599f9d5-f33b-4b1e-84be-c01981dc205b' User entered 'None (1)'	System	11 Aug 2020 03:04:50
	System	11 Aug 2020 03:04:50

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:49', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5599f9d5-f33b-4b1e-84be-c01981dc205b' User entered '10 Aug 2020 20:04'	System	11 Aug 2020 03:04:50
	System	11 Aug 2020 03:04:50

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 5'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:38', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'de046836-ef3c-4e83-9634-e70107cdd932'	System	12 Aug 2020 00:42:53
User entered 'None (1)'	System	12 Aug 2020 00:42:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:41', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'de046836-ef3c-4e83-9634-e70107cdd932'	System	12 Aug 2020 00:42:53
User entered 'No (N)'	System	12 Aug 2020 00:42:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:43', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'de046836-ef3c-4e83-9634-e70107cdd932'	System	12 Aug 2020 00:42:53
User entered 'No (N)'	System	12 Aug 2020 00:42:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'de046836-ef3c-4e83-9634-e70107cdd932'	System	12 Aug 2020 00:42:53
User entered 'None (1)'	System	12 Aug 2020 00:42:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:42:51', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'de046836-ef3c-4e83-9634-e70107cdd932'	System	12 Aug 2020 00:42:53
User entered '11 Aug 2020 17:42'	System	12 Aug 2020 00:42:53

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 6'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:02', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '950bcd6-1844-45ec-93b2-7948899fb4dc' User entered 'None (1)'	System	13 Aug 2020 03:13:18
	System	13 Aug 2020 03:13:18

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '950bcd6-1844-45ec-93b2-7948899fb4dc'	System	13 Aug 2020 03:13:18
User entered 'No (N)'	System	13 Aug 2020 03:13:18

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '950bcd6-1844-45ec-93b2-7948899fb4dc' User entered 'No (N)'	System	13 Aug 2020 03:13:18
	System	13 Aug 2020 03:13:18

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '950bcd6-1844-45ec-93b2-7948899fb4dc' User entered 'None (1)'	System	13 Aug 2020 03:13:18
	System	13 Aug 2020 03:13:18

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '950bcd6-1844-45ec-93b2-7948899fb4dc'	System	13 Aug 2020 03:13:18
User entered '12 Aug 2020 20:13'	System	13 Aug 2020 03:13:18

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 7'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd60f41bf-8f69-4da8-8c7c-a3fa406e7977'	System	14 Aug 2020 02:57:12
User entered 'None (1)'	System	14 Aug 2020 02:57:12

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:56:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd60f41bf-8f69-4da8-8c7c-a3fa406e7977'	System	14 Aug 2020 02:57:12
User entered 'No (N)'	System	14 Aug 2020 02:57:12

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:01', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd60f41bf-8f69-4da8-8c7c-a3fa406e7977'	System	14 Aug 2020 02:57:12
User entered 'No (N)'	System	14 Aug 2020 02:57:12

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:03', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd60f41bf-8f69-4da8-8c7c-a3fa406e7977'	System	14 Aug 2020 02:57:12
User entered 'None (1)'	System	14 Aug 2020 02:57:12

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd60f41bf-8f69-4da8-8c7c-a3fa406e7977'	System	14 Aug 2020 02:57:12
User entered '13 Aug 2020 19:57'	System	14 Aug 2020 02:57:12

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:54', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:57', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:07:59', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:08:01', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:08:03', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:08:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'None (0)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:08:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered 'No (N)'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T16:08:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3f65448c-a8b2-4e5a-808a-f44102e411ed' User entered '07 Aug 2020 16:08'	System	07 Aug 2020 23:08:20
	System	07 Aug 2020 23:08:20

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 15:49'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 18:19'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:41:55', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:03', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'None (0)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:13', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered 'No (N)'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-07T20:42:53', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '1e143048-1efc-4ddb-ba6e-0a0e84bc548b' User entered '07 Aug 2020 20:42'	System	08 Aug 2020 03:42:55
	System	08 Aug 2020 03:42:55

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Aug 2020 19:14'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 2'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:37', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:41', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:44', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:48', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:50', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered 'None (0)'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:41:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558'	System	08 Aug 2020 21:42:12
User entered 'No (N)'	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-08T14:42:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e0768544-5397-49ac-8c3d-1556e195a558' User entered '08 Aug 2020 14:42'	System	08 Aug 2020 21:42:12
	System	08 Aug 2020 21:42:12

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 3'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:22', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'None (0)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered 'No (N)'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-09T14:53:31', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '7e38acf5-8da1-400a-a219-7b6fe70cbd19' User entered '09 Aug 2020 14:53'	System	09 Aug 2020 21:53:34
	System	09 Aug 2020 21:53:34

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 4'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:04:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:02', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:04', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'None (0)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered 'No (N)'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-10T20:05:15', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33492d7a-0cab-40c1-ad84-907afc6f5684' User entered '10 Aug 2020 20:05'	System	11 Aug 2020 03:05:17
	System	11 Aug 2020 03:05:17

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 5'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:02', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37'	System	12 Aug 2020 00:43:33
User entered 'No interference with activity (1)'	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37'	System	12 Aug 2020 00:43:33
User entered 'No interference with activity (1)'	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:13', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37' User entered 'None (0)'	System	12 Aug 2020 00:43:33
	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37' User entered 'None (0)'	System	12 Aug 2020 00:43:33
	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37' User entered 'None (0)'	System	12 Aug 2020 00:43:33
	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:20', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37' User entered 'None (0)'	System	12 Aug 2020 00:43:33
	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37'	System	12 Aug 2020 00:43:33
User entered 'No (N)'	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-11T17:43:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '05b627b2-478c-4c95-b1de-49cca22e4c37'	System	12 Aug 2020 00:43:33
User entered '11 Aug 2020 17:43'	System	12 Aug 2020 00:43:33

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 6'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:20', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:25', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:27', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:31', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88' User entered 'None (0)'	System	13 Aug 2020 03:13:47
	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88'	System	13 Aug 2020 03:13:47
User entered 'No (N)'	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-12T20:13:42', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9db8ddee-634f-4231-8d30-51dabf7f0b88'	System	13 Aug 2020 03:13:47
User entered '12 Aug 2020 20:13'	System	13 Aug 2020 03:13:47

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 7'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:15', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'None (0)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8'	System	14 Aug 2020 02:57:42
User entered 'No interference with activity (1)'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'None (0)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:25', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'None (0)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:27', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'None (0)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'None (0)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:31', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered 'No (N)'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-13T19:57:40', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '92344920-85f7-4495-84a0-e03202cd46d8' User entered '13 Aug 2020 19:57'	System	14 Aug 2020 02:57:42
	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	14 Aug 2020 02:57:42
User entered 'Day 8'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-14T19:31:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '83cb3115-b9ac-4657-8c11-10e3e790e743' User entered 'None (0)'	System	15 Aug 2020 02:31:16
	System	15 Aug 2020 02:31:16

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-14T19:31:13', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '83cb3115-b9ac-4657-8c11-10e3e790e743'	System	15 Aug 2020 02:31:16
User entered '14 Aug 2020 19:31'	System	15 Aug 2020 02:31:16

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	14 Aug 2020 02:57:42
User entered 'Day 8'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-14T19:31:17', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd72afbea-ba58-4597-a526-9499dd4939be' User entered 'No (N)'	System	15 Aug 2020 02:31:26
	System	15 Aug 2020 02:31:26

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-08-14T19:31:20', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd72afbea-ba58-4597-a526-9499dd4939be' User entered '14 Aug 2020 19:31'	System	15 Aug 2020 02:31:26
	System	15 Aug 2020 02:31:26

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 02:57:42

US3262133

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 02:57:42

US3262133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:46:52

US3262133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:46:52

US3262133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:46:52

US3262133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4)	(b) (4), (b) (6)
		05 Oct 2020 13:46:52

US3262133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:30:14

US3262133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Sep 2020 18:30:14

US3262133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:49:20

US3262133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:49:20

US3262133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:49:20

US3262133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:49:20

US3262133

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:30:19

US3262133

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Sep 2020 18:30:19

US3262133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:54:31

US3262133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:54:31

US3262133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:54:31

US3262133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:54:31

US3262133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 18:30:49

US3262133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Sep 2020 18:30:49

US3262133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:05

US3262133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:05
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:31:05

US3262133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'VISIT2'	System	05 Sep 2020 18:31:05

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Sep 2020 18:32:47
User entered '10:35' reason for change: Data Entry Error	Daisy Langarica (b) (4)	05 Sep 2020 18:32:47
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	System	05 Sep 2020 18:32:34
	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '05 Sep 2020 10:35'	System	05 Sep 2020 18:32:47
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:47
Query 'Data is required. Please provide.' answered by System	System	05 Sep 2020 18:32:47
data change (Site from System).		
User entered '98.0' F reason for change: Data Entry	Daisy Langarica (b) (4)	05 Sep 2020 18:32:47
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Oral (Oral)'	(b) (4) Daisy Langerica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '73'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'bpm'	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '16'	(b) (4) Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'breaths/min'	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '130'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '77'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Oct 2020 15:06:18
User entered '11:45' reason for change: Data Entry Error	Alia Bober (b) (4)	30 Oct 2020 15:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '05 Sep 2020 11:45'	System	30 Oct 2020 15:06:18
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Oct 2020 15:06:18
User entered '98.2' F reason for change: Data Entry Error	Alia Bober (b) (4)	30 Oct 2020 15:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Oct 2020 15:06:18
User entered '69' reason for change: Data Entry Error	Alia Bober (b) (4)	30 Oct 2020 15:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'bpm'	System	30 Oct 2020 15:06:18
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System	System	30 Oct 2020 15:06:18
data change (Site from System).		
User entered '13' reason for change: Data Entry	Alia Bober (b) (4)	30 Oct 2020 15:06:18
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'breaths/min'	System	30 Oct 2020 15:06:18
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Oct 2020 15:06:18
User entered '120' reason for change: Data Entry Error	Alia Bober (b) (4)	30 Oct 2020 15:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	30 Oct 2020 15:06:18
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 15:06:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Oct 2020 15:06:18
User entered '80' reason for change: Data Entry Error	Alia Bober (b) (4)	30 Oct 2020 15:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 18:32:34
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:32:34
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	30 Oct 2020 15:06:18
User entered empty.	System	05 Sep 2020 18:32:34

US3262133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:12

US3262133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langerica (b) (4)	05 Sep 2020 18:31:12

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	05 Sep 2020 18:53:50
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	05 Sep 2020 18:53:50
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	05 Sep 2020 18:36:03
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	05 Sep 2020 18:36:03
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:36:03
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:36:03
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 18:36:03

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:36:03
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '11:15' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Sep 2020 18:53:50
User entered empty.	Daisy Langarica (b) (4)	05 Sep 2020 18:36:03
	(b) (4)	

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '05 Sep 2020 11:15'	System	05 Sep 2020 18:53:50
User entered empty.	System	05 Sep 2020 18:36:03

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:36:03

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'ONCE'	System	05 Sep 2020 18:36:03

US3262133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:17:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 18:36:03

US3262133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:37

US3262133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:37

US3262133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '10:39'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:37

US3262133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '05 Sep 2020 10:39'	System	05 Sep 2020 18:31:37

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:17:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '10:37'	(b) (4) Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '05 Sep 2020 10:37'	System	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered empty.	System	05 Sep 2020 18:31:52

US3262133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	05 Sep 2020 18:31:56

US3262133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Sep 2020 18:31:56

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '23c90b3d-e675-4b66-9352-24669f683828' User entered 'Yes (Y)'	System	05 Sep 2020 18:56:27
	System	05 Sep 2020 18:56:27

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '23c90b3d-e675-4b66-9352-24669f683828' User entered '98.2'	System	05 Sep 2020 18:56:27
	System	05 Sep 2020 18:56:27

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '23c90b3d-e675-4b66-9352-24669f683828'	System	05 Sep 2020 18:56:27
User entered 'No (N)'	System	05 Sep 2020 18:56:27

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '23c90b3d-e675-4b66-9352-24669f683828' User entered '05 Sep 2020 11:56'	System	05 Sep 2020 18:56:27
	System	05 Sep 2020 18:56:27

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 11:35'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 14:05'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '139d67d2-278c-46ca-b805-c339cdb106d6' User entered 'Yes (Y)'	System	06 Sep 2020 01:55:30
	System	06 Sep 2020 01:55:30

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '139d67d2-278c-46ca-b805-c339cdb106d6' User entered '98.6'	System	06 Sep 2020 01:55:30
	System	06 Sep 2020 01:55:30

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '139d67d2-278c-46ca-b805-c339cdb106d6' User entered 'No (N)'	System	06 Sep 2020 01:55:30
	System	06 Sep 2020 01:55:30

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:27', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '139d67d2-278c-46ca-b805-c339cdb106d6'	System	06 Sep 2020 01:55:30
User entered '05 Sep 2020 18:55'	System	06 Sep 2020 01:55:30

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 15:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 2'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9' User entered 'Yes (Y)'	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:20', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9' User entered '101.2'	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9'	System	06 Sep 2020 20:16:48
User entered 'Yes (Y)'	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).		31 Mar 2021 09:45:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:37', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9' User entered '1'	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:37', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9' User entered '0'	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3d3ba7a7-0fbc-453e-b568-dd0e48b9bed9' User entered '06 Sep 2020 13:16'	System	06 Sep 2020 20:16:48
	System	06 Sep 2020 20:16:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 3'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:05:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a0ecbd59-264b-4d66-8b5b-ebc233628b63'	System	07 Sep 2020 19:06:01
User entered 'Yes (Y)'	System	07 Sep 2020 19:06:01

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:05:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a0ecbd59-264b-4d66-8b5b-ebc233628b63' User entered '99.6'	System	07 Sep 2020 19:06:01
	System	07 Sep 2020 19:06:01

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:05:50', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a0ecbd59-264b-4d66-8b5b-ebc233628b63'	System	07 Sep 2020 19:06:01
User entered 'No (N)'	System	07 Sep 2020 19:06:01

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:05:57', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a0ecbd59-264b-4d66-8b5b-ebc233628b63' User entered '07 Sep 2020 12:05'	System	07 Sep 2020 19:06:01
	System	07 Sep 2020 19:06:01

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 4'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:15:45', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9efad323-56e3-4b8b-9525-87793d5637d8' User entered 'Yes (Y)'	System	09 Sep 2020 03:15:58
	System	09 Sep 2020 03:15:58

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:15:50', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9efad323-56e3-4b8b-9525-87793d5637d8' User entered '97.8'	System	09 Sep 2020 03:15:58
	System	09 Sep 2020 03:15:58

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:15:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9efad323-56e3-4b8b-9525-87793d5637d8' User entered 'No (N)'	System	09 Sep 2020 03:15:58
	System	09 Sep 2020 03:15:58

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:15:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9efad323-56e3-4b8b-9525-87793d5637d8' User entered '08 Sep 2020 20:15'	System	09 Sep 2020 03:15:58
	System	09 Sep 2020 03:15:58

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 5'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:58:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b754ab34-a775-4601-ac5c-abcdcd517d54'	System	10 Sep 2020 01:59:02
User entered 'Yes (Y)'	System	10 Sep 2020 01:59:02

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:58:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b754ab34-a775-4601-ac5c-abcdcd517d54' User entered '98.2'	System	10 Sep 2020 01:59:02
	System	10 Sep 2020 01:59:02

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:58:54', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b754ab34-a775-4601-ac5c-abcdcd517d54'	System	10 Sep 2020 01:59:02
User entered 'No (N)'	System	10 Sep 2020 01:59:02

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:58:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b754ab34-a775-4601-ac5c-abcddcd517d54' User entered '09 Sep 2020 18:58'	System	10 Sep 2020 01:59:02
	System	10 Sep 2020 01:59:02

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 6'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 7'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:46:35', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5eb038cd-ac14-4744-82a0-ea6e8de7f26f' User entered 'Yes (Y)'	System	12 Sep 2020 00:54:18
	System	12 Sep 2020 00:54:18

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:46:40', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5eb038cd-ac14-4744-82a0-ea6e8de7f26f' User entered '98.2'	System	12 Sep 2020 00:54:18
	System	12 Sep 2020 00:54:18

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:46:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5eb038cd-ac14-4744-82a0-ea6e8de7f26f' User entered 'No (N)'	System	12 Sep 2020 00:54:18
	System	12 Sep 2020 00:54:18

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:46:51', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '5eb038cd-ac14-4744-82a0-ea6e8de7f26f' User entered '11 Sep 2020 17:46'	System	12 Sep 2020 00:54:18
	System	12 Sep 2020 00:54:18

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75a5f807-da57-493e-9a2d-4950caf402b9'	System	05 Sep 2020 18:56:43
User entered 'None (1)'	System	05 Sep 2020 18:56:43

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75a5f807-da57-493e-9a2d-4950caf402b9'	System	05 Sep 2020 18:56:43
User entered 'No (N)'	System	05 Sep 2020 18:56:43

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75a5f807-da57-493e-9a2d-4950caf402b9'	System	05 Sep 2020 18:56:43
User entered 'No (N)'	System	05 Sep 2020 18:56:43

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:36', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75a5f807-da57-493e-9a2d-4950caf402b9' User entered 'None (1)'	System	05 Sep 2020 18:56:43
	System	05 Sep 2020 18:56:43

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75a5f807-da57-493e-9a2d-4950caf402b9' User entered '05 Sep 2020 11:56'	System	05 Sep 2020 18:56:43
	System	05 Sep 2020 18:56:43

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 11:35'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 14:05'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:33', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3fdf3c45-784d-4ae9-be79-0d5d18bfc1fd'	System	06 Sep 2020 01:55:49
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:55:49

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:36', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3fdf3c45-784d-4ae9-be79-0d5d18bfc1fd' User entered 'No (N)'	System	06 Sep 2020 01:55:49
	System	06 Sep 2020 01:55:49

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3fdf3c45-784d-4ae9-be79-0d5d18bfc1fd' User entered 'No (N)'	System	06 Sep 2020 01:55:49
	System	06 Sep 2020 01:55:49

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:41', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3fdf3c45-784d-4ae9-be79-0d5d18bfc1fd'	System	06 Sep 2020 01:55:49
User entered 'None (1)'	System	06 Sep 2020 01:55:49

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3fdf3c45-784d-4ae9-be79-0d5d18bfc1fd' User entered '05 Sep 2020 18:55'	System	06 Sep 2020 01:55:49
	System	06 Sep 2020 01:55:49

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 15:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 2'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:53', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6f6a15a4-ee1c-4963-803c-91a45664a74a'	System	06 Sep 2020 20:17:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 20:17:10

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6f6a15a4-ee1c-4963-803c-91a45664a74a' User entered 'No (N)'	System	06 Sep 2020 20:17:10
	System	06 Sep 2020 20:17:10

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:16:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6f6a15a4-ee1c-4963-803c-91a45664a74a' User entered 'No (N)'	System	06 Sep 2020 20:17:10
	System	06 Sep 2020 20:17:10

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6f6a15a4-ee1c-4963-803c-91a45664a74a' User entered 'None (1)'	System	06 Sep 2020 20:17:10
	System	06 Sep 2020 20:17:10

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6f6a15a4-ee1c-4963-803c-91a45664a74a' User entered '06 Sep 2020 13:17'	System	06 Sep 2020 20:17:10
	System	06 Sep 2020 20:17:10

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 3'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:06:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a'	System	07 Sep 2020 19:07:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:06:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a' User entered 'Yes (Y)'	System	07 Sep 2020 19:07:12
	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:06:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a' User entered '70'	System	07 Sep 2020 19:07:12
	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:06:42', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a' User entered 'No (N)'	System	07 Sep 2020 19:07:12
	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:06:45', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a'	System	07 Sep 2020 19:07:12
User entered 'None (1)'	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75710bbc-9506-4205-95a0-0ea6a7d1a73a' User entered '07 Sep 2020 12:07'	System	07 Sep 2020 19:07:12
	System	07 Sep 2020 19:07:12

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 4'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:01', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0dd816fe-5907-480a-a2ed-3e357402bad0'	System	09 Sep 2020 03:16:19
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 03:16:19

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0dd816fe-5907-480a-a2ed-3e357402bad0' User entered 'No (N)'	System	09 Sep 2020 03:16:19
	System	09 Sep 2020 03:16:19

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:09', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0dd816fe-5907-480a-a2ed-3e357402bad0' User entered 'No (N)'	System	09 Sep 2020 03:16:19
	System	09 Sep 2020 03:16:19

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:12', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0dd816fe-5907-480a-a2ed-3e357402bad0' User entered 'None (1)'	System	09 Sep 2020 03:16:19
	System	09 Sep 2020 03:16:19

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '0dd816fe-5907-480a-a2ed-3e357402bad0'	System	09 Sep 2020 03:16:19
User entered '08 Sep 2020 20:16'	System	09 Sep 2020 03:16:19

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 5'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:02', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e2bc5279-1b7a-4059-adac-914baf7395c0'	System	10 Sep 2020 01:59:26
User entered 'None (1)'	System	10 Sep 2020 01:59:26

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e2bc5279-1b7a-4059-adac-914baf7395c0'	System	10 Sep 2020 01:59:26
User entered 'No (N)'	System	10 Sep 2020 01:59:26

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e2bc5279-1b7a-4059-adac-914baf7395c0' User entered 'No (N)'	System	10 Sep 2020 01:59:26
	System	10 Sep 2020 01:59:26

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:10', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e2bc5279-1b7a-4059-adac-914baf7395c0'	System	10 Sep 2020 01:59:26
User entered 'None (1)'	System	10 Sep 2020 01:59:26

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:22', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e2bc5279-1b7a-4059-adac-914baf7395c0' User entered '09 Sep 2020 18:59'	System	10 Sep 2020 01:59:26
	System	10 Sep 2020 01:59:26

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 6'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 7'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3b78df3e-6f7f-4da8-85b9-63618c377ad7'	System	12 Sep 2020 00:54:22
User entered 'None (1)'	System	12 Sep 2020 00:54:22

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:03', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3b78df3e-6f7f-4da8-85b9-63618c377ad7'	System	12 Sep 2020 00:54:22
User entered 'No (N)'	System	12 Sep 2020 00:54:22

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3b78df3e-6f7f-4da8-85b9-63618c377ad7'	System	12 Sep 2020 00:54:22
User entered 'No (N)'	System	12 Sep 2020 00:54:22

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3b78df3e-6f7f-4da8-85b9-63618c377ad7'	System	12 Sep 2020 00:54:22
User entered 'None (1)'	System	12 Sep 2020 00:54:22

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:12', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3b78df3e-6f7f-4da8-85b9-63618c377ad7'	System	12 Sep 2020 00:54:22
User entered '11 Sep 2020 17:47'	System	12 Sep 2020 00:54:22

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:43', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:48', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:50', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:52', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:54', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5' User entered 'None (0)'	System	05 Sep 2020 18:57:10
	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:56:57', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5'	System	05 Sep 2020 18:57:10
User entered 'No (N)'	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T11:57:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b25f039c-6d1a-418f-93bf-ee86518c83e5'	System	05 Sep 2020 18:57:10
User entered '05 Sep 2020 11:57'	System	05 Sep 2020 18:57:10

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 11:35'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 14:05'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:51', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'None (0)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:54', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b'	System	06 Sep 2020 01:56:16
User entered 'Some interference with activity (2)'	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:57', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'None (0)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:55:59', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'None (0)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:56:01', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'None (0)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:56:04', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'None (0)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:56:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered 'No (N)'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-05T18:56:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cde72377-e518-489a-84bb-09f817aa849b' User entered '05 Sep 2020 18:56'	System	06 Sep 2020 01:56:16
	System	06 Sep 2020 01:56:16

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '05 Sep 2020 15:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 2'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0'	System	06 Sep 2020 20:17:59
User entered 'No interference with activity (1)'	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:15', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0'	System	06 Sep 2020 20:17:59
User entered 'Some interference with activity (2)'	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered 'No interference with activity (1)'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered 'None (0)'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:26', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered 'None (0)'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered 'None (0)'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:43', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered 'Yes (Y)'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-06T13:17:55', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'aaf33702-1f43-4f6a-b8b9-51fd87bcc7a0' User entered '06 Sep 2020 13:17'	System	06 Sep 2020 20:17:59
	System	06 Sep 2020 20:17:59

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 3'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:15', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa'	System	07 Sep 2020 19:07:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa'	System	07 Sep 2020 19:07:48
User entered 'Some interference with activity (2)'	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa'	System	07 Sep 2020 19:07:48
User entered 'Some interference with activity (2)'	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:26', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa' User entered 'None (0)'	System	07 Sep 2020 19:07:48
	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa' User entered 'None (0)'	System	07 Sep 2020 19:07:48
	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:33', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa' User entered 'None (0)'	System	07 Sep 2020 19:07:48
	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:35', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa' User entered 'No (N)'	System	07 Sep 2020 19:07:48
	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-07T12:07:44', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f3e21c93-136f-45b4-8351-0698c36c76fa' User entered '07 Sep 2020 12:07'	System	07 Sep 2020 19:07:48
	System	07 Sep 2020 19:07:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 4'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'No interference with activity (1)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'No interference with activity (1)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'None (0)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:26', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'None (0)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'None (0)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:30', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'None (0)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered 'No (N)'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-08T20:16:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '24844f2c-487f-4a2f-a58d-d413e608e38f' User entered '08 Sep 2020 20:16'	System	09 Sep 2020 03:16:42
	System	09 Sep 2020 03:16:42

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 5'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:26', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:30', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:32', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:36', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:37', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'None (0)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:39', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered 'No (N)'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-09T18:59:46', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '3ddad408-e720-45e0-8079-28bf136acb53' User entered '09 Sep 2020 18:59'	System	10 Sep 2020 01:59:48
	System	10 Sep 2020 01:59:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 6'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
Data entry locked.	System	05 Sep 2020 18:53:50
User entered 'Day 7'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:23', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:27', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066' User entered 'None (0)'	System	12 Sep 2020 00:54:31
	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

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)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:29', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066'	System	12 Sep 2020 00:54:31
User entered 'No (N)'	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-09-11T17:47:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '6cb0c0c4-93b1-4b75-94d3-858509c99066'	System	12 Sep 2020 00:54:31
User entered '11 Sep 2020 17:47'	System	12 Sep 2020 00:54:31

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:53:50

US3262133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:17:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:48
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:53:50

US3262133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:05:30

US3262133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:05:30

US3262133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:05:30

US3262133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:05:30

US3262133

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:05:37

US3262133

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Oct 2020 14:05:37

US3262133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:08:13

US3262133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:08:13

US3262133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:08:13

US3262133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:08:13

US3262133

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:08:19

US3262133

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Oct 2020 14:08:19

US3262133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:13:13

US3262133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:13:13

US3262133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:13:13

US3262133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:13:13

US3262133

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:13:19

US3262133

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Oct 2020 14:13:19

US3262133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:03:04

US3262133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:03:04

US3262133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:03:04

US3262133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'VISIT3'	System	09 Oct 2020 14:03:04

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07:55'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '07 Oct 2020 07:55'	System	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'bpm'	System	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'breaths/min'	System	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '139'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '89'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'mmHg'	System	09 Oct 2020 14:09:41

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03

US3262133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03

US3262133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:47

US3262133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:09:47

US3262133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:10:34

US3262133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:10:34

US3262133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered '08:03'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:10:34

US3262133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered '07 Oct 2020 08:03'	System	09 Oct 2020 14:10:34

US3262133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:10:40

US3262133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	09 Oct 2020 14:10:40

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 64'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-07T08:08:14', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4006edd1-7623-4ea3-877e-20c0f20d0b23'	System	07 Oct 2020 15:08:27
User entered 'No (N)'	System	07 Oct 2020 15:08:27

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-07T08:08:17', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4006edd1-7623-4ea3-877e-20c0f20d0b23'	System	07 Oct 2020 15:08:27
User entered 'No (N)'	System	07 Oct 2020 15:08:27

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-07T08:08:22', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '4006edd1-7623-4ea3-877e-20c0f20d0b23' User entered '07 Oct 2020 08:08:22'	System	07 Oct 2020 15:08:27
	System	07 Oct 2020 15:08:27

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 71'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-14T21:20:15', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b21f09fa-012f-4e4c-8a8a-52a3a44488ed' User entered 'No (N)'	System	15 Oct 2020 04:20:23
	System	15 Oct 2020 04:20:23

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-14T21:20:18', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b21f09fa-012f-4e4c-8a8a-52a3a44488ed' User entered 'No (N)'	System	15 Oct 2020 04:20:23
	System	15 Oct 2020 04:20:23

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-14T21:20:21', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'b21f09fa-012f-4e4c-8a8a-52a3a44488ed' User entered '14 Oct 2020 21:20:21'	System	15 Oct 2020 04:20:23
	System	15 Oct 2020 04:20:23

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 78'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-22T21:11:02', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33550af8-29d1-4f43-ba22-b8277aada036'	System	23 Oct 2020 04:11:14
User entered 'No (N)'	System	23 Oct 2020 04:11:14

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-22T21:11:06', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33550af8-29d1-4f43-ba22-b8277aada036'	System	23 Oct 2020 04:11:14
User entered 'No (N)'	System	23 Oct 2020 04:11:14

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-10-22T21:11:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '33550af8-29d1-4f43-ba22-b8277aada036' User entered '22 Oct 2020 21:11:11'	System	23 Oct 2020 04:11:14
	System	23 Oct 2020 04:11:14

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 92'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-06T22:11:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e96eae18-de60-4e91-bf27-8164fd5e4ea5'	System	07 Nov 2020 06:11:25
User entered 'No (N)'	System	07 Nov 2020 06:11:25

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-06T22:11:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e96eae18-de60-4e91-bf27-8164fd5e4ea5' User entered 'No (N)'	System	07 Nov 2020 06:11:25
	System	07 Nov 2020 06:11:25

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-06T22:11:22', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'e96eae18-de60-4e91-bf27-8164fd5e4ea5' User entered '06 Nov 2020 22:11:22'	System	07 Nov 2020 06:11:25
	System	07 Nov 2020 06:11:25

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 99'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:12', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2'	System	11 Nov 2020 22:50:58
User entered 'Yes (Y)'	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:19', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2'	System	11 Nov 2020 22:50:58
User entered 'No (N)'	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:24', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2'	System	11 Nov 2020 22:50:58
User entered 'No (N)'	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:28', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2'	System	11 Nov 2020 22:50:58
User entered 'Yes (Y)'	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:34', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2'	System	11 Nov 2020 22:50:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-11T14:50:47', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '75d6ffc4-e00f-4a48-9f12-5d653ea565a2' User entered '11 Nov 2020 14:50:47'	System	11 Nov 2020 22:50:58
	System	11 Nov 2020 22:50:58

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16
Data entry locked.	System	07 Aug 2020 23:04:54
User entered 'Day 106'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 23:04:54

US3262133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:25:16
Data entry locked.	System	07 Aug 2020 23:04:54
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 23:04:54

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-25T23:26:04', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14b7801b-22aa-43cc-a75a-92cff3b87670'	System	26 Nov 2020 07:26:21
User entered 'No (N)'	System	26 Nov 2020 07:26:21

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-25T23:26:07', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14b7801b-22aa-43cc-a75a-92cff3b87670' User entered 'No (N)'	System	26 Nov 2020 07:26:21

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-11-25T23:26:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '14b7801b-22aa-43cc-a75a-92cff3b87670'	System	26 Nov 2020 07:26:21
User entered '25 Nov 2020 23:26:16'	System	26 Nov 2020 07:26:21

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-08T20:22:22', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a6b13079-7ec8-434f-9dc4-1623ba0219c3'	System	09 Dec 2020 04:22:46
User entered 'No (N)'	System	09 Dec 2020 04:22:46

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-08T20:22:36', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a6b13079-7ec8-434f-9dc4-1623ba0219c3' User entered 'No (N)'	System	09 Dec 2020 04:22:46

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-08T20:22:43', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a6b13079-7ec8-434f-9dc4-1623ba0219c3' User entered '08 Dec 2020 20:22:43'	System	09 Dec 2020 04:22:46
	System	09 Dec 2020 04:22:46

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-23T17:54:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd4c17d33-fc20-4498-a02c-96cfd765e672'	System	24 Dec 2020 01:55:08
User entered 'No (N)'	System	24 Dec 2020 01:55:08

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-23T17:55:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd4c17d33-fc20-4498-a02c-96cfd765e672' User entered 'No (N)'	System	24 Dec 2020 01:55:08
	System	24 Dec 2020 01:55:08

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2020-12-23T17:55:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'd4c17d33-fc20-4498-a02c-96cfd765e672' User entered '23 Dec 2020 17:55:05'	System	24 Dec 2020 01:55:08
	System	24 Dec 2020 01:55:08

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-14T19:20:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f826f13a-a14d-43bb-840e-73d55f0050ed' User entered 'No (N)'	System	15 Jan 2021 03:20:11

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-14T19:20:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f826f13a-a14d-43bb-840e-73d55f0050ed' User entered 'No (N)'	System	15 Jan 2021 03:20:11

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-14T19:20:08', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f826f13a-a14d-43bb-840e-73d55f0050ed' User entered '14 Jan 2021 19:20:08'	System	15 Jan 2021 03:20:11

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-18T18:38:54', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'c816b877-7a0d-4667-b92b-20e2fca2bd38'	System	19 Jan 2021 02:39:02
User entered 'No (N)'	System	19 Jan 2021 02:39:02

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-18T18:38:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'c816b877-7a0d-4667-b92b-20e2fca2bd38'	System	19 Jan 2021 02:39:02
User entered 'No (N)'	System	19 Jan 2021 02:39:02

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-18T18:38:59', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'c816b877-7a0d-4667-b92b-20e2fca2bd38'	System	19 Jan 2021 02:39:02
User entered '18 Jan 2021 18:38:59'	System	19 Jan 2021 02:39:02

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-26T12:28:30', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '578c9bd1-328b-424a-8368-871e5c89686e' User entered 'No (N)'	System	26 Jan 2021 21:18:29
	System	26 Jan 2021 21:18:29

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-26T12:28:33', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '578c9bd1-328b-424a-8368-871e5c89686e' User entered 'No (N)'	System	26 Jan 2021 21:18:29

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-01-26T12:28:36', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '578c9bd1-328b-424a-8368-871e5c89686e' User entered '26 Jan 2021 12:28:36'	System	26 Jan 2021 21:18:29
	System	26 Jan 2021 21:18:29

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-02-02T19:54:53', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f2efd863-cedc-43da-9348-068605da6343'	System	03 Feb 2021 03:55:01
User entered 'No (N)'	System	03 Feb 2021 03:55:01

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-02-02T19:54:56', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f2efd863-cedc-43da-9348-068605da6343'	System	03 Feb 2021 03:55:01
User entered 'No (N)'	System	03 Feb 2021 03:55:01

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-02-02T19:54:59', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f2efd863-cedc-43da-9348-068605da6343'	System	03 Feb 2021 03:55:01
User entered '02 Feb 2021 19:54:59'	System	03 Feb 2021 03:55:01

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-03T21:46:58', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '88e919bb-5e43-43c1-b93d-4687a055e313'	System	04 Mar 2021 05:47:10
User entered 'No (N)'	System	04 Mar 2021 05:47:10

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-03T21:47:01', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '88e919bb-5e43-43c1-b93d-4687a055e313'	System	04 Mar 2021 05:47:10
User entered 'No (N)'	System	04 Mar 2021 05:47:10

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-03T21:47:05', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '88e919bb-5e43-43c1-b93d-4687a055e313'	System	04 Mar 2021 05:47:10
User entered '03 Mar 2021 21:47:05'	System	04 Mar 2021 05:47:10

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:14:39-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb' User entered 'Yes (Y)'	System	12 Mar 2021 00:15:19
	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:14:43-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb' User entered 'No (N)'	System	12 Mar 2021 00:15:19
	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:14:47-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb' User entered 'No (N)'	System	12 Mar 2021 00:15:19
	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:14:52-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb' User entered 'Yes (Y)'	System	12 Mar 2021 00:15:19
	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:14:57-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb'	System	12 Mar 2021 00:15:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-11T16:15:09-08:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '9183da42-7214-496a-a7e7-c4f7a61975cb' User entered '11 Mar 2021 16:15:09'	System	12 Mar 2021 00:15:19
	System	12 Mar 2021 00:15:19

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-22T12:17:45-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cf180c58-7d31-4910-8e7b-4e83e228ab25'	System	22 Mar 2021 19:18:30
User entered 'No (N)'	System	22 Mar 2021 19:18:30

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-22T12:17:48-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cf180c58-7d31-4910-8e7b-4e83e228ab25'	System	22 Mar 2021 19:18:30
User entered 'No (N)'	System	22 Mar 2021 19:18:30

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-22T12:17:54-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'cf180c58-7d31-4910-8e7b-4e83e228ab25' User entered '22 Mar 2021 12:17:54'	System	22 Mar 2021 19:18:30
	System	22 Mar 2021 19:18:30

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-08T19:16:46-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '297f2269-6f09-44a5-a705-aea289b739c7' User entered 'No (N)'	System	09 Apr 2021 02:16:59
	System	09 Apr 2021 02:16:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-08T19:16:49-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '297f2269-6f09-44a5-a705-aea289b739c7'	System	09 Apr 2021 02:16:59
User entered 'No (N)'	System	09 Apr 2021 02:16:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-08T19:16:56-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: '297f2269-6f09-44a5-a705-aea289b739c7'	System	09 Apr 2021 02:16:59
User entered '08 Apr 2021 19:16:56'	System	09 Apr 2021 02:16:59

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-15T12:50:43-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a07176a0-3675-4b35-9cbe-7806cc1c6898'	System	15 Apr 2021 19:51:09
User entered 'No (N)'	System	15 Apr 2021 19:51:09

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Have you been exposed to someone with 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 (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-15T12:50:45-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a07176a0-3675-4b35-9cbe-7806cc1c6898' User entered 'No (N)'	System	15 Apr 2021 19:51:09

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-04-15T12:50:50-07:00', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'a07176a0-3675-4b35-9cbe-7806cc1c6898'	System	15 Apr 2021 19:51:09
User entered '15 Apr 2021 12:50:50'	System	15 Apr 2021 19:51:09

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:25:16

US3262133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:17:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:25:16
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:25:16

US3262133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:17:39

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)	30 Apr 2021 15:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-03T21:47:11', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f382ac74-18eb-4e52-896e-94f499f1f3ed'	System	04 Mar 2021 05:47:18
User entered 'No (N)'	System	04 Mar 2021 05:47:18

US3262133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:17:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D64E284E-42A5-4494-AC9F-6961A25B35F6)', Time: '2021-03-03T21:47:16', User OID: 'PatientReportedOutcome (US3262133)', ODM File OID: 'f382ac74-18eb-4e52-896e-94f499f1f3ed'	System	04 Mar 2021 05:47:18
User entered '03 Mar 2021 21:47:16'	System	04 Mar 2021 05:47:18

US3262133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:50:14

US3262133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:19
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:50:14

US3262133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:50:14

US3262133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:19
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:50:14

US3262133

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:44:29

US3262133

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:35:03
User entered 'I'	System	05 Jan 2021 15:44:29

US3262133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 15:45:29

US3262133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered '07 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 15:45:29

US3262133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 15:45:29

US3262133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 15:45:29

US3262133

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 15:45:33

US3262133

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User entered 'I'	System	05 Jan 2021 15:45:33

US3262133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 19:13:40

US3262133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered '05 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 19:13:40

US3262133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 19:13:40

US3262133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:13:40

US3262133

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 19:13:44

US3262133

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User entered 'I'	System	05 Jan 2021 19:13:44

US3262133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langerica (b) (4)	06 Feb 2021 00:02:55
	(b) (4)	

US3262133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered '03 Feb 2021'	Daisy Langarica (b) (4)	06 Feb 2021 00:02:55
	(b) (4)	

US3262133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:34:26
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	06 Feb 2021 00:02:55

US3262133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:17:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	06 Feb 2021 00:02:55
	(b) (4)	

US3262133

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	06 Feb 2021 00:03:13
	(b) (4)	

US3262133

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User entered 'I'	System	06 Feb 2021 00:03:13

US3262133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:16:30

US3262133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	24 Mar 2021 10:47:40
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'correct' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 22:16:46
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 22:16:30
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 22:16:30

US3262133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:16:30

US3262133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'VISIT4'	System	22 Mar 2021 22:16:30

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '22 Mar 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '12:06'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered '22 Mar 2021 12:06'	System	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '99.2' F	(b) (4) Daisy Langarica (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered empty.	(b) (4) Daisy Langarica (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '85'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'bpm'	System	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '14'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'breaths/min'	System	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '119'	(b) (4) Daisy Langarica (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'mmHg'	System	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '70'	(b) (4) Daisy Langarica (b) (4) (b) (4)	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'mmHg'	System	01 Apr 2021 00:03:51

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:17:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:16:54

US3262133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:17:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:16:54

US3262133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:18:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22MAR2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:27:35
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22MAR2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' ' answered with 'correct as is - VISIT HAS BEEN ENTERED IN PRECLARUS ACCESSION KIT NO 1F650809569 IMMUNO 1: 1F602123431 IMMNUNO 2: 1F623160935 THANKS! ALL SAMPLES SHIPPED - NO QUERIES FOR THIS SUBJECTS VISIT LOADED' (Site from DM).	Daisy Langerica (b) (4) (b) (4)	09 Apr 2021 23:42:43
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22MAR2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:45:29
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 22:18:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '12:15'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:18:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered '22 Mar 2021 12:15'	System	22 Mar 2021 22:18:19

US3262133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 22:18:24

US3262133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:17:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'I'	System	22 Mar 2021 22:18:24

US3262133

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:00

US3262133

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:00

US3262133

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:00

US3262133

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

Form: Visit Date

Generated On: 09 Jun 2021 16:17:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 19:32:00

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '0'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:00:13
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:26:57

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Daisy Langarica (b) (4)	31 Mar 2021 21:00:13
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 03:26:57

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered empty.	System	28 Jan 2021 19:32:16

US3262133

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

Form: Unblinding

Generated On: 09 Jun 2021 16:17:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered empty.	System	28 Jan 2021 19:32:16

US3262133

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:31

US3262133

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 19:32:31

US3262133

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '10:24'	(b) (4), (b) (6)	28 Jan 2021 19:32:31

US3262133

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered '28 Jan 2021 10:24'	System	28 Jan 2021 19:32:31

US3262133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:32:44

US3262133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 19:32:44

US3262133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User entered '10:22'	(b) (4), (b) (6)	28 Jan 2021 19:32:44

US3262133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:23:19
User entered '28 Jan 2021 10:22'	System	28 Jan 2021 19:32:44

US3262133

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:17:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:08:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:49:02

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:55:18
Data point term sent to Coder	System	12 Oct 2020 17:54:06
User entered 'Sinus Infection'	(b) (4), (b) (6)	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 20:33:14
User closed query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).		19 Apr 2021 15:01:01
Query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' answered with 'UPDATED' (Site from DM).	Daisy Langarica (b) (4)	09 Apr 2021 23:44:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	09 Apr 2021 23:43:51
	(b) (4)	
User opened query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:40:32
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 18:57:27
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated.' (Site from DM).	Alia Bober (b) (4)	24 Nov 2020 17:22:39
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 05:44:30

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '29 Sep 2020'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Yes (Y)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:33:14
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'None (NONE)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'I'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Unknown (UNKNOWN)'		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:17:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 17:53:40

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User closed query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 08:46:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylaxis - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 20:58:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 20:58:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:33:14
Query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' answered with 'AS PER PI VERBALLY CONFIRMED THIS DOES NOT MEET SERIOUS EVENT AS THIS HAS NOTHING TO DO WITH STUDY DRUG ' (Site from DM).	Daisy Langarica (b) (4)	20 Apr 2021 20:00:50
	(b) (4)	
Data point term sent to Coder	System	20 Apr 2021 18:38:39
Coding entries removed.	Daisy Langarica (b) (4)	20 Apr 2021 18:38:18
	(b) (4)	
User entered 'ANAPHYLAXIS unknown cause' reason for change: Data Entry Error	Daisy Langarica (b) (4)	20 Apr 2021 18:38:18
	(b) (4)	
User opened query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 23:49:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylaxis - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 17:28:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 17:28:34
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 17:25:57
User entered 'Anaphylaxis'	Alia Bober (b) (4)	24 Nov 2020 17:24:58
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 08:47:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:33:14
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' answered with 'updated - and pending PIs response fo: Per MM, please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 18:40:22
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 18:38:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:33:28
User entered 'No (N)' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:30:23
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:27:29
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '07 Nov 2020'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User closed query 'Per CDM: Response noted, Kindly remove time.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:25:53
Query 'Per CDM: Response noted, Kindly remove time.' answered with 'Start time is not required, because the time is not within 24 hours of dosing.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:34:13
User entered empty; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:33:28
User opened query 'Per CDM: Response noted, Kindly remove time.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:42:13
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).	(b) (4), (b) (6)	03 Dec 2020 16:41:11
Comment added 'Time is recorded in source.'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:26:09
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Per query time not documented.' (Site from System).	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:25:35
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	24 Nov 2020 17:24:58
User entered '08:30'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User entered empty.	System	25 Feb 2021 15:33:28
User entered '07 Nov 2020 08:30'	System	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '07 Nov 2020'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User closed query 'Per CDM: Response noted however, 'End Time' is not required, unless end time is within 24 hours of dosing (05-SEP-2020_11:15am), Please review and leave this data field blank. Thanks' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:26:08
Query 'Per CDM: Response noted however, 'End Time' is not required, unless end time is within 24 hours of dosing (05-SEP-2020_11:15am), Please review and leave this data field blank. Thanks' answered with 'End time is not required, because the time is not within 24 hours of dosing.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:34:20
User entered empty; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:33:28
User opened query 'Per CDM: Response noted however, 'End Time' is not required, unless end time is within 24 hours of dosing (05-SEP-2020_11:15am), Please review and leave this data field blank. Thanks' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 10:27:09
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).		12 Dec 2020 10:25:43
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Time is recorded in source.' (Site from System).	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:26:02
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	24 Nov 2020 17:24:58
User entered '08:45'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User entered empty.	System	25 Feb 2021 15:33:28
User entered '07 Nov 2020 08:45'	System	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'None (NONE)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:26:30
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'Epinephrine auto injector con med is listed.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:37:07
User entered '0' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Feb 2021 15:36:24
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:27:36
User entered '1'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '1' reason for change: Data Entry Error	Alia Bober (b) (4)	25 Feb 2021 15:36:24
User entered '0'	(b) (4) Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.	Alia Bober (b) (4) (b) (4)	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User entered '0'	System	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36
User entered '1'	System	24 Nov 2020 17:24:58

US3262133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:36

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:07:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:57:49
User entered		
'USA-US069-2021-mRNA-1273-P301000003'	System	23 Mar 2021 16:57:37
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:57:37
User entered 'New' reason for change: Data Entry Error		23 Mar 2021 16:57:37
Reviewed for Safety.		23 Mar 2021 16:56:59
User entered empty.		23 Mar 2021 16:56:19
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:07:26
User coded data point as SOC: Hepatobiliary disorders, HLGT: Bile duct disorders, HLT: Bile duct infections and inflammations, PT: Biliary colic, LLT: Biliary colic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:29:32
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:29:32
Data point term sent to Coder	System	22 Mar 2021 20:15:55
User entered 'epigastric pain due to recurrent biliary colic'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:07:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:07:47
User entered 'No (N)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:09
User entered 'No (N)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:14
User entered '08 Mar 2021'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:20
User entered empty.		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:26
User entered 'No (N)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:12:30
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:12:36
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:30:31
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 20:29:25
DataPoint Verified.		20 Apr 2021 20:29:20
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 16:01:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 16:01:13
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 16:01:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 20:15:02
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not Alia Bober required.	(b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:12:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:44
User entered '0'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:12:48
User entered '0'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:29:30
User closed query 'PV Query: As per the narrative section on the CRF, hospital admission (08Mar2021) and discharge (10Mar2021) dates are provided. Please confirm if the subject was hospitalized for this event? If Yes then kindly check the seriousness criteria of hospitalization. If No then kindly provide the details on why the patient was hospitalized on these dates.' (Site from Safety).		12 Apr 2021 14:45:07
Query 'PV Query: As per the narrative section on the CRF, hospital admission (08Mar2021) and discharge (10Mar2021) dates are provided. Please confirm if the subject was hospitalized for this event? If Yes then kindly check the seriousness criteria of hospitalization. If No then kindly provide the details on why the patient was hospitalized on these dates.' answered with 'UPDATED ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	09 Apr 2021 23:50:41
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Apr 2021 23:47:26
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Apr 2021 23:47:26
User entered '1' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	09 Apr 2021 23:47:26
User opened query 'PV Query: As per the narrative section on the CRF, hospital admission (08Mar2021) and discharge (10Mar2021) dates are provided. Please confirm if the subject was hospitalized for this event? If Yes then kindly check the seriousness criteria of hospitalization. If No then kindly provide the details on why the patient was hospitalized on these dates.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 11:59:38
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	22 Mar 2021 20:15:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

1755 of 2178

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:02
User entered '08 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:10
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:28
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:35
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:39
User entered '0'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:46
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 20:29:48
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		13 Apr 2021 13:35:25
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'UPDATED' (Site from Safety).		12 Apr 2021 16:04:08
User entered 'Not Related (NOT RELATED)' reason for change: New Information		12 Apr 2021 16:03:59
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		30 Mar 2021 11:59:17
User entered 'Not Applicable (NOT APPLICABLE)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 20:29:53
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly' (Site from Safety).		13 Apr 2021 13:35:27
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly answered with 'UPDATED ' (Site from Safety).		12 Apr 2021 16:04:14
User entered 'Not Related (NOT RELATED)' reason for change: New Information		12 Apr 2021 16:03:59
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly' (Site from Safety).		30 Mar 2021 11:59:09
User entered 'Not Applicable (NOT APPLICABLE)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 20:29:59
User closed query 'PV Query: As the last dose of study drug was given on 5 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		13 Apr 2021 13:35:28
Query 'PV Query: As the last dose of study drug was given on 5 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED ' (Site from Safety).		12 Apr 2021 16:04:19
User entered 'Not Applicable (NOT APPLICABLE) reason for change: Data Entry Error		12 Apr 2021 16:03:59
User opened query 'PV Query: As the last dose of study drug was given on 5 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		30 Mar 2021 11:59:52
User entered 'None (NONE)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

None

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	07 Apr 2021 18:14:04
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:30:04
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:30:09
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 15:02:55
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated procedures' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:57:06
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		05 Apr 2021 14:54:58
User entered 'I'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:14:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43
	(b) (4)	

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:14:29
User entered empty.		22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:30:14
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		14 Apr 2021 13:39:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		14 Apr 2021 13:39:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		14 Apr 2021 13:38:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		14 Apr 2021 13:38:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no information at this time waiting on medical records ' (Site from Safety).		13 Apr 2021 16:43:11
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated based on records site has no other information at this time ' (Site from Safety).		13 Apr 2021 16:42:54

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'cholecystectomy' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 16:41:30
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'unknown' (Site from Safety).		13 Apr 2021 16:40:54
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'faxed 4/12/2021' (Site from Safety).		13 Apr 2021 16:38:10
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		05 Apr 2021 00:12:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 11:58:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Mar 2021 11:58:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Mar 2021 11:58:37
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		30 Mar 2021 11:58:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Mar 2021 20:15:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

1773 of 2178

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.		22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4) (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 20:15:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Mar 2021 20:10:21
DataPoint inactivated with code reason code Data not required.	Alia Bober (b) (4)	25 Nov 2020 16:02:43

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:24:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:24:12
Data point term sent to Coder	System	12 Apr 2021 20:46:00
User entered 'urinary tract infection'	(b) (4), (b) (6)	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '1 Feb 2021'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User entered empty.	System	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '24 Feb 2021'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User entered empty.	System	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'No (N)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Not Related (NOT RELATED)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'None (NONE)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'l'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered '0'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:33:14
User entered empty.		12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User entered '0'	System	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47
User entered 'I'	System	12 Apr 2021 20:45:02

US3262133

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:17:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:47

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:17:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:13:04
User closed query 'Per CDM: Response/updates noted however, there is no corresponding CM recorded for Diary Dose 2 Day 3 Headache? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response/updates noted however, there is no corresponding CM recorded for Diary Dose 2 Day 3 Headache? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'corrected con med' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:51:25
User opened query 'Per CDM: Response/updates noted however, there is no corresponding CM recorded for Diary Dose 2 Day 3 Headache? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		12 Apr 2021 20:54:39
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Dose 2 Day 2 and 3 Pain at Injection Site, Dose 2 Day 3 Headache = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		30 Mar 2021 09:29:09
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Dose 2 Day 2 and 3 Pain at Injection Site, Dose 2 Day 3 Headache = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).		30 Mar 2021 09:23:50
		29 Mar 2021 17:31:04

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Dose 2 Day 2 and 3 Pain at Injection Site, Dose 2 Day 3 Headache = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:35:17
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:12:34

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:14:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:14:59
Data point term sent to Coder	System	06 Oct 2020 14:13:21
User entered 'Allegra'	Alia Bober (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:13:19

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:08:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:08:14
Data point term sent to Coder	System	06 Oct 2020 14:15:22
User entered 'Lansoprazole'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastric esophageal reflux disease'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:14:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:10:16
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:10:16
Data point term sent to Coder	System	06 Oct 2020 14:16:24
User entered 'Citoprolam'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:49:31
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:49:31
User entered empty.	Alia Bober (b) (4)	06 Oct 2020 14:15:25
	(b) (4)	

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:15:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:46:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:46:44
Data point term sent to Coder	System	06 Oct 2020 14:17:27
User entered 'Famotidine'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastric esophageal reflux disease'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:16:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:58:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:58:18
Data point term sent to Coder	System	12 Oct 2020 17:57:13
User closed query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' (Site from System).	System	12 Oct 2020 17:57:09
Query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 17:57:09
User entered 'Amlodipine' reason for change: Data Entry Error		12 Oct 2020 17:56:56
User opened query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 20:56:07
Data point term sent to Coder	System	06 Oct 2020 14:17:29
User entered 'Hypertension'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:56:56
User entered 'Amlodipine'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:17:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:19:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:19:12
Data point term sent to Coder	System	06 Oct 2020 14:18:30
User entered 'Lisinopril'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:17:58

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:57:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:57:15
Data point term sent to Coder	System	12 Oct 2020 17:56:11
User entered 'Cefdinir'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Sinus Infection'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:56:02

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 06:30:53
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 06:30:53
Data point term sent to Coder	System	12 Nov 2020 00:08:24
Data point term sent to Coder	System	12 Nov 2020 00:06:21
User entered 'EPINEPHRINE AUTO-INJECTOR'	(b) (4), (b) (6) (b) (4)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:44:33
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.		22 Mar 2021 19:48:11
' answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Per Query Resolution		22 Mar 2021 19:47:59
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		11 Mar 2021 09:11:37
User entered 'Yes (Y)'		12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:07:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 00:07:35
User entered 'ANAPHYLAXIS REACTION' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 00:07:35
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:06:03
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 00:42:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 00:42:53
User entered '0.3' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 00:42:53
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:06:03
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 00:42:53
User entered 'Other (OTHER)'		12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	13 Nov 2020 00:42:53
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Nov 2020 00:06:03
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

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

Audit	User	Time (GMT)
User entered '7 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:27:24
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'End date entered and reconciled with source.' (Site from DM).	Alia Bober (b) (4)	25 Feb 2021 15:40:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 15:40:04
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:51:37
User entered 'Yes (Y)'		12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Nov 2020' reason for change: Data Entry Error	Alia Bober (b) (4)	25 Feb 2021 15:40:04
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 00:06:03

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per CDM: Thanks for the response, please keep this query in open state until data is available. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:45:13
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).		23 Apr 2021 05:45:13
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'PENDING SUBJECTS RESPONSE ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 21:45:30
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:50:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:50:50
Data point term sent to Coder	System	22 Mar 2021 19:49:58
User entered 'citalopram'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jan 2021'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 19:49:11

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:52:48
Data point term sent to Coder	System	22 Mar 2021 19:52:03
User entered 'macrobid'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:29:36
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'updated' (Site from DM).		12 Apr 2021 20:46:04
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).		30 Mar 2021 09:29:06
User entered 'urinary tract infection'		22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 19:51:09

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:54:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:54:20
Data point term sent to Coder	System	22 Mar 2021 19:53:05
User entered 'doxycycline'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:29:56
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'updated' (Site from DM).		12 Apr 2021 20:45:49
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).		30 Mar 2021 09:29:16
User entered 'urinary tract infection'		22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 19:52:07

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:54:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:54:49
Data point term sent to Coder	System	22 Mar 2021 19:54:20
User entered 'breo ellipta'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:26:39
Query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' answered with 'updated' (Site from DM).		29 Mar 2021 17:27:47
User entered 'No (N)' reason for change: Per Query Resolution		29 Mar 2021 17:27:40
User opened query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' (Site from DM).		24 Mar 2021 10:31:00
User entered 'Yes (Y)'		22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100/25'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:28:36
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit ' answered with 'updated' (Site from DM).		12 Apr 2021 20:51:39
User entered 'ug (ug)' reason for change: New Information		12 Apr 2021 20:50:53
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit ' (Site from DM).		05 Apr 2021 15:52:35
User entered 'puff (PUFF)'		22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jun 2020'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Jan 2021'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 19:53:25

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:19:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' answered with 'change in insurance provider and PCP' (Site from DM).		29 Mar 2021 17:28:21
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).		29 Mar 2021 06:55:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 20:05:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 20:05:49
Data point term sent to Coder	System	22 Mar 2021 20:04:39
User entered 'advair'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:26:04
Query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' answered with 'updated' (Site from DM).		29 Mar 2021 17:28:40
User entered 'No (N)' reason for change: Per Query Resolution		29 Mar 2021 17:28:24
User opened query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Kindly review both CM and MH pages and update accordingly, else clarify.' (Site from DM).		24 Mar 2021 10:32:25
User entered 'Yes (Y)'		22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250/50'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit. (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:28:58
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).		12 Apr 2021 20:52:32
User entered 'ug (ug)' reason for change: New Information		12 Apr 2021 20:52:27
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication recorded dose. Please update the unit as appropriate or provide explanation for alternate unit. (Site from DM).		30 Mar 2021 17:15:16
User entered 'puff (PUFF)'		22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jan 2021'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 20:04:27

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 17:31:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 17:31:17
Data point term sent to Coder	System	29 Mar 2021 17:29:54
User entered 'aleve'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain at injection site'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '440'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 17:29:45

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:55:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:55:47
Data point term sent to Coder	System	12 Apr 2021 20:55:20
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 20:54:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 17:31:19
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 Mar 2021 17:31:19
Data point term sent to Coder	System	29 Mar 2021 17:30:57
User entered 'aleve'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'FEVER AND PAIN AT INJECTION SITE, headache' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 20:54:29
User entered 'fever and pain at injection site'		29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '440'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Sep 2020'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Sep 2020'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:17:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 17:30:55

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:17:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:38:07
User closed query 'Per ETRTR: According to SAE page "Epigastric Pain due to recurrent Biliary Colic", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).		20 Apr 2021 20:38:05
Query 'Per ETRTR: According to SAE page "Epigastric Pain due to recurrent Biliary Colic", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'updated' (Site from CRA).		13 Apr 2021 16:36:47
User entered 'Yes (Y)' reason for change: New Information		12 Apr 2021 20:54:58
User opened query 'Per ETRTR: According to SAE page "Epigastric Pain due to recurrent Biliary Colic", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).		24 Mar 2021 15:50:50
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	06 Oct 2020 14:18:05

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:39

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:37:57
User entered '9 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 20:56:30

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:37:57
User entered 'robot Xi Assisted Cholecystectomy'		12 Apr 2021 20:56:30

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:37:57
User entered 'Adverse Event (AE)'		12 Apr 2021 20:56:30

US3262133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:17:39

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:37:57
User entered empty.		12 Apr 2021 20:56:30

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:28
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:21
Un-reviewed for Safety.		23 Mar 2021 16:58:17
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'USA-US069-2021-MRNA-1273-P301000003'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
Un-reviewed for Safety.	System	09 Apr 2021 23:47:26
User entered 'Yes (Y)'	System	09 Apr 2021 23:47:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Atoya'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Adams'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '2121 E. Flamingo Road'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'las vegas'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'NV'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '89119'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
User entered 'US'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 13:39:32
User entered '3'	System	13 Apr 2021 13:35:54
User entered '2'	System	12 Apr 2021 14:43:06
User entered '1'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:28
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:21
Un-reviewed for Safety.		23 Mar 2021 16:58:17
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'USA-US069-2021-MRNA-1273-P301000003'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
Un-reviewed for Safety.	System	09 Apr 2021 23:47:26
User entered 'Yes (Y)'	System	09 Apr 2021 23:47:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Atoya'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Adams'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '2121 E. Flamingo Road'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'las vegas'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'NV'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '89119'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
User entered 'US'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 13:39:32
User entered '3'	System	13 Apr 2021 13:35:54
User entered '2'	System	12 Apr 2021 14:43:06
User entered '1'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:17:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
User entered '23/Mar/2021 12:58'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:17:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
User entered 'I'		23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:28
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:21
Un-reviewed for Safety.		23 Mar 2021 16:58:17
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'USA-US069-2021-MRNA-1273-P301000003'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
Un-reviewed for Safety.	System	09 Apr 2021 23:47:26
User entered 'Yes (Y)'	System	09 Apr 2021 23:47:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Atoya'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Adams'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '2121 E. Flamingo Road'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'las vegas'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'NV'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '89119'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
User entered 'US'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 13:39:32
User entered '3'	System	13 Apr 2021 13:35:54
User entered '2'	System	12 Apr 2021 14:43:06
User entered '1'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:17:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
User entered '12/Apr/2021 09:43'	System	12 Apr 2021 14:43:06

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:17:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		13 Apr 2021 13:35:44
User entered 'I'		12 Apr 2021 14:43:06

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:28
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:21
Un-reviewed for Safety.		23 Mar 2021 16:58:17
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'USA-US069-2021-MRNA-1273-P301000003'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
Un-reviewed for Safety.	System	09 Apr 2021 23:47:26
User entered 'Yes (Y)'	System	09 Apr 2021 23:47:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Atoya'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Adams'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '2121 E. Flamingo Road'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'las vegas'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'NV'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '89119'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
User entered 'US'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 13:39:32
User entered '3'	System	13 Apr 2021 13:35:54
User entered '2'	System	12 Apr 2021 14:43:06
User entered '1'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:17:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
User entered '13/Apr/2021 08:35'	System	13 Apr 2021 13:35:54

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:17:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		14 Apr 2021 13:39:20
User entered 'I'		13 Apr 2021 13:35:54

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:28
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:21
Un-reviewed for Safety.		23 Mar 2021 16:58:17
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'USA-US069-2021-MRNA-1273-P301000003'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
Un-reviewed for Safety.	System	09 Apr 2021 23:47:26
User entered 'Yes (Y)'	System	09 Apr 2021 23:47:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'No (N)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Yes (Y)'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Atoya'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'Adams'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '2121 E. Flamingo Road'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'las vegas'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered 'NV'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4)	20 Apr 2021 20:36:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 16:58:32
Un-reviewed for Safety.		23 Mar 2021 16:58:25
Reviewed for Safety.		23 Mar 2021 16:58:13
User entered '89119'	System	23 Mar 2021 16:57:37

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
Reviewed for Safety.		12 Apr 2021 14:42:55
User entered 'US'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:17:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 13:39:32
User entered '3'	System	13 Apr 2021 13:35:54
User entered '2'	System	12 Apr 2021 14:43:06
User entered '1'	System	23 Mar 2021 16:58:38

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:17:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
User entered '14/Apr/2021 09:39'	System	14 Apr 2021 13:39:32

US3262133

Folder: SAE USA-US069-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:17:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:36:23
User entered 'I'		14 Apr 2021 13:39:32