

US3542131 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:07:20

All time stamps listed in this document are displayed in GMT

US3542131

Form: Participant Creation

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Participant ID

US3542131

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

US3542131

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Date of Informed Consent (<i>dd MMM yyyy</i>)	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	ULCERATIVE COLITIS
Start date (dd MMM yyyy)	UN UNK 1961
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 1961
Start Year (derived)	1961
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	OSTEOPENIA
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)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	ELEVATED TRIGLYCERIDES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	ILEOSTOMY
Start date (dd MMM yyyy)	UN UNK 1961
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1961
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1961
Start Year (derived)	1961
Stop Month and Year (derived)	JAN 1961
Stop Year (derived)	1961

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN DEC 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1989
Start Year (derived)	1989
Stop Month and Year (derived)	DEC 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 OCT 2018
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	OCT 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:40
Height (xxx.x)	61 in
Weight (xxx.x)	106 lb
BMI (xxx.x)	20.07040 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Date of assessment (dd MMM yyyy) 2 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN DEC 1989

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Nov 2020 21:51:49

Generated On: 10 Jun 2021 08:07:20

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

What was the participant's randomization number? 189529

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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)	02 SEP 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:40
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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)	02 SEP 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 14:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 SEP 2020
Collection time (00:00-23:59)	14:00 (24 HR)
Collection date and time (derived)	02 SEP 2020 14:00

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	02 SEP 2020 14:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 21:42:50

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

02 SEP 2020 14:54

PC Open Date & Time

02 SEP 2020 14:40

PC Close Date & Time

02 SEP 2020 17:10

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

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

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

PC Time Stamp 02 SEP 2020 21:21

PC Open Date & Time 02 SEP 2020 18:05

PC Close Date & Time 03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

04 SEP 2020 23:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 SEP 2020 23:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 07:08

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

97.2 °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

08 SEP 2020 21:38

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 14:55

PC Open Date & Time

02 SEP 2020 14:40

PC Close Date & Time

02 SEP 2020 17:10

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:22

PC Open Date & Time

02 SEP 2020 18:05

PC Close Date & Time

03 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 23:52

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 23:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 23:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

08 SEP 2020 07:08

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 21:39

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 14:56
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PC Open Date & Time	02 SEP 2020 14:40
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PC Close Date & Time	02 SEP 2020 17:10
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US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 21:23
PC Open Date & Time	02 SEP 2020 18:05
PC Close Date & Time	03 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

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 ☒

PRODUCTION RELEASE (v12.003

51 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:53
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

53 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:50
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

55 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

57 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 23:17
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 07:09
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 21:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3542131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Sep 2020 03:21:05

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Sep 2020 03:21:05

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Sep 2020 03:21:05

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Sep 2020 03:21:05

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Sep 2020 04:26:34

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:26:34

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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	VISIT2

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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)	07 OCT 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 10:54
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

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)	07 OCT 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 12:06
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3542131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 03:03:33

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020

What was the treatment time? (00:00-23:59) 11:36 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 11:36

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

What was the frequency of the study treatment dosing? ONCE

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

US3542131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

07 OCT 2020 11:00

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Jan 2021 18:13:21

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	07 OCT 2020 11:05
Nasopharyngeal Swab 2	No		

US3542131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 04:05:53

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:06

PC Open Date & Time

07 OCT 2020 11:56

PC Close Date & Time

07 OCT 2020 14:26

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 07 OCT 2020 23:09

PC Open Date & Time 07 OCT 2020 15:21

PC Close Date & Time 08 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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 OCT 2020 23:01
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 23:27

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 22:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

12 OCT 2020 00:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 23:50

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:12

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:04

PC Open Date & Time

07 OCT 2020 11:56

PC Close Date & Time

07 OCT 2020 14:26

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 23:10

PC Open Date & Time

07 OCT 2020 15:21

PC Close Date & Time

08 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 23:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 23:28

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 22:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 00:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 23:51

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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 OCT 2020 21:13

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 12:05
PC Open Date & Time	07 OCT 2020 11:56
PC Close Date & Time	07 OCT 2020 14:26

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 23:11
PC Open Date & Time	07 OCT 2020 15:21
PC Close Date & Time	08 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

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 ☒

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 23:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

99 of 1894

EAB) (1725)

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 23:28
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 22:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

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)

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US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 23:51
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:13
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3542131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Oct 2020 02:57:27

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 02:57:27

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Oct 2020 13:53:05

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Oct 2020 13:53:05

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 01:22:41

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:22:41

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Nov 2020 21:51:49

Generated On: 10 Jun 2021 08:07:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Nov 2020 04:15:23

Generated On: 10 Jun 2021 08:07:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 10:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 21:51:49

Generated On: 10 Jun 2021 08:07:20

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.

US3542131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Nov 2020 04:15:23

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 NOV 2020
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	4 NOV 2020 11:04

US3542131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:51:49

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 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"/>

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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	13 NOV 2020 13:35:31
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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	19 NOV 2020 06:32:15
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 13:20:25
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 14:43:11
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 09:21:02

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 07:13:16
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 16:19:18
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 15:39:42
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 21:24:45
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

19 JAN 2021 10:06:13

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 08:50:58

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 23:06:53
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 16:00:31

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

22 FEB 2021 15:20:28

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 08:05:55
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 08:37:57
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 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	23 MAR 2021 08:07:44
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 20:57:10

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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="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	09 APR 2021 16:01:34
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 APR 2021 17:53:01
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 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	23 APR 2021 20:33:39
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

01 MAY 2021 07:56:09

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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08 APR 2022 00:01

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12 APR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

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19 APR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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29 APR 2022 00:01

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03 MAY 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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24 MAY 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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="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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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14 JUN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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01 JUL 2022 00:01

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05 JUL 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 <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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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19 AUG 2022 00:01

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23 AUG 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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30 AUG 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

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02 SEP 2022 00:01

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06 SEP 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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"/>

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3542131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:07:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 08:05:33

US3542131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:08:18

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:08:18

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Jan 2021 03:43:27

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:43:27

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Feb 2021 22:35:16

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Feb 2021 22:35:16

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 14:56:54

Generated On: 10 Jun 2021 08:07:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542131

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 14:56:54

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 19:57:43

Generated On: 10 Jun 2021 08:07:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 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

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 19:57:43

Generated On: 10 Jun 2021 08:07:20

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 19:57:43

Generated On: 10 Jun 2021 08:07:20

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.

US3542131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 19:57:43

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	12 APR 2021
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Collection time (00:00-23:59)	14:41 (24 HR)
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Collection date and time (derived)	12 APR 2021 14:41
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US3542131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 19:57:43

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

US3542131

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542131

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:07:20

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:07:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 31 Jan 2021 19:20:27

Generated On: 10 Jun 2021 08:07:20

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

Visit date (dd MMM yyyy)	25 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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US3542131

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:44:08

Generated On: 10 Jun 2021 08:07:20

Date of updated informed consent (dd MMM yyyy) 25 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) 25 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 _____

US3542131

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Jan 2021 19:20:27

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00-23:59)	14:03 (24 HR)
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Collection date and time (derived)	25 JAN 2021 14:03
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US3542131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 31 Jan 2021 19:20:27

Generated On: 10 Jun 2021 08:07:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	14:10
Collection Date and Time (derived)	25 JAN 2021 14:10

US3542131

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Apr 2021 20:34:10

Generated On: 10 Jun 2021 08:07:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

AEID	USA-US084-2021-MRNA-1273-P30 1000009
Adverse event	ILEUS
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)	5 APR 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 APR 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)	8 APR 2021
Hospital Discharge Date (dd MMM yyyy)	10 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

PT WITH PMH OF ULCERATIVE COLITIS (S/P TOTAL COLECTOMY AND ILEOSTOMY) STARTED EXPERIENCING RUQ ABDOMINAL PAIN ON 5-APR-21. PT PRESENTED TO URGENT CARE ON 8-APR-21 AND WAS OBSERVED FOR TWO NIGHTS ON THEIR OBSERVATION/URGENT CARE UNIT. PARTICIPANT WAS DISCHARGED HOME ON 10-APR-21. CT (ABDOMEN) WAS PERFORMED ON 09APR2021 THAT SHOWED S/P COLECTOMY WITH RLQ ILEOSTOMY, AND DIFFUSELY PROMINENT LOOPS OF SMALL BOWEL WITH AIR-FLUID LEVELS SUGGESTIVE OF ILEUS. WAS MANAGED CONSERVATIVELY WITH IV HYDRATION AND IV DILAUDID (DESPITE DX OF POSSIBLE ILEUS). PAIN RESOLVED AND GAS AND STOOL VISUALIZED IN OSTEOLOGY BAG ON 10APR2021. PLAIN FILM KUB ON EVENING OF 9APR2021 SHOWED NORMAL BOWEL GAS PATTERN AND NO EVIDENCE OF ILEUS, SO WAS DISCHARGED HOME THE FOLLOWING DAY.

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

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Sep 2020 21:42:49

Generated On: 10 Jun 2021 08:07:20

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

Yes ☒

No ☐

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

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication LOPID

Prophylaxis Yes ☐
No ☒

Indication ELEVATED TRIGLYCERIDES

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	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	2000
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"/>

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	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)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication RIGHT UPPER QUADRANT
ABDOMINAL PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication RUQ ABDOMINAL PAIN

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 APR 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"/>

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Name of Medication HYDROMORPHONE (DILAUDID)

Prophylaxis Yes ☐
No ☒

Indication RUQ ABDOMINAL PAIN

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	10 APR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 APR 2021	X-RAY ABDOMEN	Adverse Event	
09 APR 2021	CT ABDOMEN/ P/E PELVIS WITH CONTRAST	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:07:20

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:07:20

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 ☐

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

SAEID	USA-US084-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

SAEID	USA-US084-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 12:02
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

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

SAEID	USA-US084-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 06:30
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

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 20:28:27

Generated On: 10 Jun 2021 08:07:20

SAEID	USA-US084-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 14:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3542131 (Prod: George Washington University)

US3542131

Form: Participant Creation

Generated On: 10 Jun 2021 08:07:20

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:57:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'US3542131'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:34:30

US3542131

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:37

US3542131

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:34:31

US3542131

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:37

US3542131

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'SCRN'	System	02 Sep 2020 17:53:37

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:34:32

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '71'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'YEARS'	System	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '71'	System	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'l'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:07:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:53:54

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:23:43
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:23:43
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Sep 2020'	System	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2020'	System	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:09

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:34:31

US3542131

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:07:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'l'	System	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:07:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:03

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:44:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:44:48
Data point term sent to Coder	System	10 Sep 2020 17:43:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ULCERATIVE COLITIS 2) ILEOSTOMY' (Site from System).	System	10 Sep 2020 17:42:27
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ULCERATIVE COLITIS 2) ILEOSTOMY' answered with 'Event split into two terms' (Site from System).	Hannah Yellin (b) (4)	10 Sep 2020 17:42:27
Data point term sent to Coder	System	10 Sep 2020 17:42:14
Signature has been broken.	Hannah Yellin (b) (4)	10 Sep 2020 17:41:41
User entered 'ULCERATIVE COLITIS' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	10 Sep 2020 17:41:41
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ULCERATIVE COLITIS 2) ILEOSTOMY'	Coder Import (b) (4)	08 Sep 2020 11:44:39

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
' (Site from System).		
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 18:56:41
User entered 'Ulcerative Colitis s/p ileostomy'	Madhu Balachandran	03 Sep 2020 18:56:34
	(b) (4)	

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 1961'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 1961'	System	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '1961'	System	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:56:34

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 18:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 18:58:45
Data point term sent to Coder	System	03 Sep 2020 18:57:42
User entered 'Osteopenia'	Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 2008'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 2008'	System	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2008'	System	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:56:46

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 18:59:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 18:59:50
Data point term sent to Coder	System	03 Sep 2020 18:58:46
User entered 'Osteoporosis'	Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 2000'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 2008'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 2000'	System	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2000'	System	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 2008'	System	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2008'	System	03 Sep 2020 18:58:15

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglyceride increased - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 19:00:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 19:00:40
Data point term sent to Coder	System	03 Sep 2020 18:59:49
User entered 'Elevated Triglycerides'	Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 2000'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 2000'	System	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2000'	System	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	03 Sep 2020 18:59:24

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Ileostomy, LLT: Ileostomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
Data point term sent to Coder	System	10 Sep 2020 17:42:14
User entered 'ILEOSTOMY'	Hannah Yellin (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'un UNK 1961'	(b) (4) Hannah Yellin (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'un UNK 1961'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 1961'	System	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '1961'	System	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Jan 1961'	System	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '1961'	System	10 Sep 2020 17:42:07

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:27:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:27:36
Data point term sent to Coder	System	04 Nov 2020 22:26:52
User entered 'Bilateral tubal ligation'	David Diemert (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'un Dec 1989'	(b) (4) David Diemert (b) (4) (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'un Dec 1989'	(b) (4) David Diemert (b) (4) (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Dec 1989'	System	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '1989'	System	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Dec 1989'	System	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '1989'	System	04 Nov 2020 22:26:39

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:21:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:21:56
Data point term sent to Coder	System	22 Apr 2021 17:20:35
User entered 'Cervical radiculopathy'	Taylor Ladson (b) (4)	22 Apr 2021 17:19:53

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	22 Apr 2021 17:20:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Taylor Ladson (b) (4)	22 Apr 2021 17:20:05
User entered 'un UNK unk' (non-conformant).	(b) (4)	
	System	22 Apr 2021 17:19:53
	Taylor Ladson (b) (4)	22 Apr 2021 17:19:53
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '1' reason for change: Data Entry Error	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:20:05
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:19:53

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:19:53

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 17:22:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:22:58
Data point term sent to Coder	System	22 Apr 2021 17:21:36
User entered 'BILATERAL CATARACTs' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:20:40
Data point term sent to Coder	System	22 Apr 2021 17:20:35
User entered 'bilateral cataract'	Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'l'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '03 Oct 2018'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'Oct 2018'	System	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '2018'	System	22 Apr 2021 17:20:30

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:22:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:22:58
Data point term sent to Coder	System	22 Apr 2021 17:21:36
User entered 'endometriosis'	Taylor Ladson (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	22 Apr 2021 17:21:02

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:25:42
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:25:42
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '13:40'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '02 Sep 2020 13:40'	System	21 Jan 2021 19:25:42
User entered '2 Sep 2020 13:40'	System	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '61' in	(b) (4)	
	Madhu Balachandran	03 Sep 2020 19:00:46
DataPoint set to visible.	(b) (4)	
	System	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '106' lb	(b) (4) Madhu Balachandran	03 Sep 2020 19:00:46
DataPoint set to visible.	(b) (4) System	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '20.07040'	System	03 Sep 2020 19:00:46
DataPoint set to visible.	System	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'kg/m2'	System	03 Sep 2020 19:00:46
DataPoint set to visible.	System	02 Sep 2020 17:54:13

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'bpm'	System	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'breaths/min'	System	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'mmHg'	System	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'mmHg'	System	03 Sep 2020 19:00:46

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34

US3542131

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34

US3542131

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:26:01
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Jan 2021 19:26:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:00:52

US3542131

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:26:01
User entered '02 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	21 Jan 2021 19:26:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	Madhu Balachandran (b) (4)	03 Sep 2020 19:00:52

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:54:56
Query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Added to MH eCRF.' (Site from DM).	David Diemert (b) (4) (b) (4)	04 Nov 2020 22:25:56
User opened query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 08:45:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:42:50
User entered 'Surgically sterile (SURGICALLY STERILE)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN Dec 1989'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:07:20

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:11

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

[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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

[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)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

[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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'I'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:07:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:01:51

US3542131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:26

US3542131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:26:32
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:26:32
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 17:54:26

US3542131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:54:26

US3542131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'VISIT1'	System	02 Sep 2020 17:54:26

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:54:29

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered '189529'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:54:29

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 17:54:29

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:38

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:38

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 18:25:38

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:38

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:25:38

US3542131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 21:51:49
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	11 Nov 2020 19:57:09
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:56:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:56:16

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Pre-Dose (PREDOSE)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:26:56
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:26:56
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '13:40'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '02 Sep 2020 13:40'	System	21 Jan 2021 19:26:56
User entered '2 Sep 2020 13:40'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '98.0' F	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '73'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'bpm'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '12'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'breaths/min'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '117'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '76'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:07:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Post-Dose (POSTDOSE)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:27:13
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:27:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '14:50'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '02 Sep 2020 14:50'	System	21 Jan 2021 19:27:13
User entered '2 Sep 2020 14:50'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '97.9' F	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '77'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'bpm'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '16'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'breaths/min'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '107'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '69'	Madhu Balachandran (b) (4)	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	03 Sep 2020 19:05:45

US3542131

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:27:39
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Jan 2021 19:27:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:02

US3542131

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:27:39
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Jan 2021 19:27:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:02

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:27:54
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:27:54
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered '14:20'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '02 Sep 2020 14:20'	System	21 Jan 2021 19:27:54
User entered '2 Sep 2020 14:20'	System	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:42:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'ONCE'	System	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 18:26:03

US3542131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:16

US3542131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:28:04
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:28:04
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:16

US3542131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '14:00'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:16

US3542131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '02 Sep 2020 14:00'	System	21 Jan 2021 19:28:04
User entered '2 Sep 2020 14:00'	System	03 Sep 2020 19:06:16

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:28:14
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '2 Sep 2020'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:42:50
User entered '14:05'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '02 Sep 2020 14:05'	System	21 Jan 2021 19:28:14
User entered '2 Sep 2020 14:05'	System	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered empty.	System	03 Sep 2020 19:06:28

US3542131

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	03 Sep 2020 19:06:33

US3542131

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'I'	System	03 Sep 2020 19:06:33

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:54:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6304acd9-eb48-447b-9f00-c3a4b47c4939'	System	02 Sep 2020 18:54:54
User entered 'Yes (Y)'	System	02 Sep 2020 18:54:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:54:35', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6304acd9-eb48-447b-9f00-c3a4b47c4939' User entered '97.9'	System	02 Sep 2020 18:54:54
	System	02 Sep 2020 18:54:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:54:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6304acd9-eb48-447b-9f00-c3a4b47c4939'	System	02 Sep 2020 18:54:54
User entered 'No (N)'	System	02 Sep 2020 18:54:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:54:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6304acd9-eb48-447b-9f00-c3a4b47c4939'	System	02 Sep 2020 18:54:54
User entered '02 Sep 2020 14:54'	System	02 Sep 2020 18:54:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 14:40'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d'	System	03 Sep 2020 01:21:37
User entered 'Yes (Y)'	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:08', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d' User entered '97.0'	System	03 Sep 2020 01:21:37
	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:13', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d'	System	03 Sep 2020 01:21:37
User entered 'Yes (Y)'	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
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 'Participant was contacted.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 06:55:39
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.'	Madhu Balachandran	10 Sep 2020 19:07:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d'	(b) (4)	
User entered '1'	System	03 Sep 2020 01:21:37
	System	03 Sep 2020 01:21:37
	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d'	System	03 Sep 2020 01:21:37
User entered '0'	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '48e44bab-19d9-4121-861f-68a85f7e8b8d'	System	03 Sep 2020 01:21:37
User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:37

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 18:05'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 2'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:51:33', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b08429d0-844c-40b7-b2e5-8c78957aa475'	System	04 Sep 2020 03:51:57
User entered 'Yes (Y)'	System	04 Sep 2020 03:51:57

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:51:39', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b08429d0-844c-40b7-b2e5-8c78957aa475' User entered '97.7'	System	04 Sep 2020 03:51:57
	System	04 Sep 2020 03:51:57

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:51:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b08429d0-844c-40b7-b2e5-8c78957aa475'	System	04 Sep 2020 03:51:57
User entered 'No (N)'	System	04 Sep 2020 03:51:57

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:51:55', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b08429d0-844c-40b7-b2e5-8c78957aa475'	System	04 Sep 2020 03:51:57
User entered '03 Sep 2020 23:51'	System	04 Sep 2020 03:51:57

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 3'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:48:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '51a8fa0b-de01-4faf-bada-341d0b5ab5a8'	System	05 Sep 2020 03:49:11
User entered 'Yes (Y)'	System	05 Sep 2020 03:49:11

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:48:59', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '51a8fa0b-de01-4faf-bada-341d0b5ab5a8'	System	05 Sep 2020 03:49:11
User entered '97.2'	System	05 Sep 2020 03:49:11

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '51a8fa0b-de01-4faf-bada-341d0b5ab5a8'	System	05 Sep 2020 03:49:11
User entered 'No (N)'	System	05 Sep 2020 03:49:11

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:08', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '51a8fa0b-de01-4faf-bada-341d0b5ab5a8'	System	05 Sep 2020 03:49:11
User entered '04 Sep 2020 23:49'	System	05 Sep 2020 03:49:11

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 4'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '2f3392a1-d886-4089-8a1e-c383c78b2131'	System	06 Sep 2020 02:45:22
User entered 'Yes (Y)'	System	06 Sep 2020 02:45:22

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '2f3392a1-d886-4089-8a1e-c383c78b2131' User entered '97.0'	System	06 Sep 2020 02:45:22
	System	06 Sep 2020 02:45:22

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '2f3392a1-d886-4089-8a1e-c383c78b2131'	System	06 Sep 2020 02:45:22
User entered 'No (N)'	System	06 Sep 2020 02:45:22

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '2f3392a1-d886-4089-8a1e-c383c78b2131'	System	06 Sep 2020 02:45:22
User entered '05 Sep 2020 22:45'	System	06 Sep 2020 02:45:22

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 5'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9ffc7471-8e38-45e5-8e1b-d5409d7ffcd1'	System	07 Sep 2020 03:16:44
User entered 'Yes (Y)'	System	07 Sep 2020 03:16:44

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:32', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9ffc7471-8e38-45e5-8e1b-d5409d7ffcd1'	System	07 Sep 2020 03:16:44
User entered '97.9'	System	07 Sep 2020 03:16:44

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:36', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9ffc7471-8e38-45e5-8e1b-d5409d7ffcd1'	System	07 Sep 2020 03:16:44
User entered 'No (N)'	System	07 Sep 2020 03:16:44

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:42', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9ffc7471-8e38-45e5-8e1b-d5409d7ffcd1'	System	07 Sep 2020 03:16:44
User entered '06 Sep 2020 23:16'	System	07 Sep 2020 03:16:44

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 6'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:13', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '605dca86-b8e3-4989-b6ad-6b07062d537e'	System	08 Sep 2020 11:08:27
User entered 'Yes (Y)'	System	08 Sep 2020 11:08:27

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '605dca86-b8e3-4989-b6ad-6b07062d537e' User entered '97.8'	System	08 Sep 2020 11:08:27
	System	08 Sep 2020 11:08:27

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:21', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '605dca86-b8e3-4989-b6ad-6b07062d537e'	System	08 Sep 2020 11:08:27
User entered 'No (N)'	System	08 Sep 2020 11:08:27

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:23', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '605dca86-b8e3-4989-b6ad-6b07062d537e'	System	08 Sep 2020 11:08:27
User entered '08 Sep 2020 07:08'	System	08 Sep 2020 11:08:27

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 7'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:38:42', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '530474b8-cbf3-430b-b071-39187f30520a'	System	09 Sep 2020 01:55:54
User entered 'Yes (Y)'	System	09 Sep 2020 01:55:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:38:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '530474b8-cbf3-430b-b071-39187f30520a' User entered '97.2'	System	09 Sep 2020 01:55:54
	System	09 Sep 2020 01:55:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:38:52', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '530474b8-cbf3-430b-b071-39187f30520a'	System	09 Sep 2020 01:55:54
User entered 'No (N)'	System	09 Sep 2020 01:55:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:38:57', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '530474b8-cbf3-430b-b071-39187f30520a'	System	09 Sep 2020 01:55:54
User entered '08 Sep 2020 21:38'	System	09 Sep 2020 01:55:54

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9279f0c7-ce5d-4451-83cc-140bd061be97'	System	02 Sep 2020 18:55:39
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 18:55:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:24', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9279f0c7-ce5d-4451-83cc-140bd061be97'	System	02 Sep 2020 18:55:39
User entered 'No (N)'	System	02 Sep 2020 18:55:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:27', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9279f0c7-ce5d-4451-83cc-140bd061be97'	System	02 Sep 2020 18:55:39
User entered 'No (N)'	System	02 Sep 2020 18:55:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:32', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9279f0c7-ce5d-4451-83cc-140bd061be97'	System	02 Sep 2020 18:55:39
User entered 'None (1)'	System	02 Sep 2020 18:55:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '9279f0c7-ce5d-4451-83cc-140bd061be97'	System	02 Sep 2020 18:55:39
User entered '02 Sep 2020 14:55'	System	02 Sep 2020 18:55:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 14:40'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99c53d2d-7339-49a2-9b03-14679393c3a7'	System	03 Sep 2020 01:22:23
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 01:22:23

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:21:58', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99c53d2d-7339-49a2-9b03-14679393c3a7'	System	03 Sep 2020 01:22:23
User entered 'No (N)'	System	03 Sep 2020 01:22:23

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:01', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99c53d2d-7339-49a2-9b03-14679393c3a7'	System	03 Sep 2020 01:22:23
User entered 'No (N)'	System	03 Sep 2020 01:22:23

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99c53d2d-7339-49a2-9b03-14679393c3a7'	System	03 Sep 2020 01:22:23
User entered 'None (1)'	System	03 Sep 2020 01:22:23

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99c53d2d-7339-49a2-9b03-14679393c3a7'	System	03 Sep 2020 01:22:23
User entered '02 Sep 2020 21:22'	System	03 Sep 2020 01:22:23

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 18:05'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 2'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:02', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '34ba8248-7b1c-470c-8b23-f36f0e3a0ece'	System	04 Sep 2020 03:52:39
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 03:52:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '34ba8248-7b1c-470c-8b23-f36f0e3a0ece'	System	04 Sep 2020 03:52:39
User entered 'No (N)'	System	04 Sep 2020 03:52:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:23', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '34ba8248-7b1c-470c-8b23-f36f0e3a0ece'	System	04 Sep 2020 03:52:39
User entered 'No (N)'	System	04 Sep 2020 03:52:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:33', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '34ba8248-7b1c-470c-8b23-f36f0e3a0ece'	System	04 Sep 2020 03:52:39
User entered 'None (1)'	System	04 Sep 2020 03:52:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '34ba8248-7b1c-470c-8b23-f36f0e3a0ece'	System	04 Sep 2020 03:52:39
User entered '03 Sep 2020 23:52'	System	04 Sep 2020 03:52:39

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 3'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e92265a-2a97-4e60-bf63-7b03d27034d8'	System	05 Sep 2020 03:49:38
User entered 'None (1)'	System	05 Sep 2020 03:49:38

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e92265a-2a97-4e60-bf63-7b03d27034d8'	System	05 Sep 2020 03:49:38
User entered 'No (N)'	System	05 Sep 2020 03:49:38

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:24', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e92265a-2a97-4e60-bf63-7b03d27034d8'	System	05 Sep 2020 03:49:38
User entered 'No (N)'	System	05 Sep 2020 03:49:38

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e92265a-2a97-4e60-bf63-7b03d27034d8'	System	05 Sep 2020 03:49:38
User entered 'None (1)'	System	05 Sep 2020 03:49:38

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:35', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e92265a-2a97-4e60-bf63-7b03d27034d8'	System	05 Sep 2020 03:49:38
User entered '04 Sep 2020 23:49'	System	05 Sep 2020 03:49:38

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 4'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:26', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6797d923-b5ef-4d68-939a-1824e86a773a'	System	06 Sep 2020 02:45:51
User entered 'None (1)'	System	06 Sep 2020 02:45:51

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:30', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6797d923-b5ef-4d68-939a-1824e86a773a'	System	06 Sep 2020 02:45:51
User entered 'No (N)'	System	06 Sep 2020 02:45:51

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6797d923-b5ef-4d68-939a-1824e86a773a'	System	06 Sep 2020 02:45:51
User entered 'No (N)'	System	06 Sep 2020 02:45:51

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:46', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6797d923-b5ef-4d68-939a-1824e86a773a'	System	06 Sep 2020 02:45:51
User entered 'None (1)'	System	06 Sep 2020 02:45:51

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6797d923-b5ef-4d68-939a-1824e86a773a'	System	06 Sep 2020 02:45:51
User entered '05 Sep 2020 22:45'	System	06 Sep 2020 02:45:51

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 5'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ac90ae7e-55c9-4af6-9995-785f9e5f20a8'	System	07 Sep 2020 03:17:05
User entered 'None (1)'	System	07 Sep 2020 03:17:05

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ac90ae7e-55c9-4af6-9995-785f9e5f20a8'	System	07 Sep 2020 03:17:05
User entered 'No (N)'	System	07 Sep 2020 03:17:05

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:16:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ac90ae7e-55c9-4af6-9995-785f9e5f20a8'	System	07 Sep 2020 03:17:05
User entered 'No (N)'	System	07 Sep 2020 03:17:05

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ac90ae7e-55c9-4af6-9995-785f9e5f20a8'	System	07 Sep 2020 03:17:05
User entered 'None (1)'	System	07 Sep 2020 03:17:05

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ac90ae7e-55c9-4af6-9995-785f9e5f20a8'	System	07 Sep 2020 03:17:05
User entered '06 Sep 2020 23:17'	System	07 Sep 2020 03:17:05

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 6'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'd9b51569-bb8f-49af-aa01-2a623cc7cfd1'	System	08 Sep 2020 11:08:43
User entered 'None (1)'	System	08 Sep 2020 11:08:43

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'd9b51569-bb8f-49af-aa01-2a623cc7cfd1'	System	08 Sep 2020 11:08:43
User entered 'No (N)'	System	08 Sep 2020 11:08:43

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'd9b51569-bb8f-49af-aa01-2a623cc7cfd1'	System	08 Sep 2020 11:08:43
User entered 'No (N)'	System	08 Sep 2020 11:08:43

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:36', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'd9b51569-bb8f-49af-aa01-2a623cc7cfd1'	System	08 Sep 2020 11:08:43
User entered 'None (1)'	System	08 Sep 2020 11:08:43

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:39', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'd9b51569-bb8f-49af-aa01-2a623cc7cfd1'	System	08 Sep 2020 11:08:43
User entered '08 Sep 2020 07:08'	System	08 Sep 2020 11:08:43

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 7'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '42038e30-95b9-4d8c-92bb-6a7b77416cb2'	System	09 Sep 2020 01:56:17
User entered 'None (1)'	System	09 Sep 2020 01:56:17

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '42038e30-95b9-4d8c-92bb-6a7b77416cb2'	System	09 Sep 2020 01:56:17
User entered 'No (N)'	System	09 Sep 2020 01:56:17

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '42038e30-95b9-4d8c-92bb-6a7b77416cb2'	System	09 Sep 2020 01:56:17
User entered 'No (N)'	System	09 Sep 2020 01:56:17

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '42038e30-95b9-4d8c-92bb-6a7b77416cb2'	System	09 Sep 2020 01:56:17
User entered 'None (1)'	System	09 Sep 2020 01:56:17

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '42038e30-95b9-4d8c-92bb-6a7b77416cb2'	System	09 Sep 2020 01:56:17
User entered '08 Sep 2020 21:39'	System	09 Sep 2020 01:56:17

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:49', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:52', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:57', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:55:59', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'None (0)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:56:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered 'No (N)'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T14:56:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b9b80df0-95cf-4d30-9b1d-21784e962e29'	System	02 Sep 2020 18:56:09
User entered '02 Sep 2020 14:56'	System	02 Sep 2020 18:56:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 14:40'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:41', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:22:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:23:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'None (0)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:23:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered 'No (N)'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-02T21:23:13', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8cbc1fd0-b753-49e3-b86d-13f48836ca49'	System	03 Sep 2020 01:23:15
User entered '02 Sep 2020 21:23'	System	03 Sep 2020 01:23:15

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '02 Sep 2020 18:05'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 2'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:56', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:52:59', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'None (0)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:53:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered 'No (N)'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-03T23:53:14', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b42e10e5-2800-4926-92a7-74511f0cbfb2'	System	04 Sep 2020 03:53:17
User entered '03 Sep 2020 23:53'	System	04 Sep 2020 03:53:17

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 3'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:40', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:49', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:52', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:49:56', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'None (0)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:50:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered 'No (N)'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-04T23:50:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '67a246f8-162c-4d61-acc0-9e9e0a6a88d0'	System	05 Sep 2020 03:50:13
User entered '04 Sep 2020 23:50'	System	05 Sep 2020 03:50:13

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 4'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:56', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:45:59', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:15', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'None (0)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered 'No (N)'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-05T22:46:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8fa7d87d-18fb-4ba0-b657-4fc12163927d'	System	06 Sep 2020 02:46:26
User entered '05 Sep 2020 22:46'	System	06 Sep 2020 02:46:26

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 5'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:10', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:14', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'None (0)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered 'No (N)'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-06T23:17:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'de6ec2ab-91ca-4344-90a3-07cfac03a2ab'	System	07 Sep 2020 03:17:30
User entered '06 Sep 2020 23:17'	System	07 Sep 2020 03:17:30

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 6'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:49', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'None (0)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:08:57', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered 'No (N)'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T07:09:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b863dcc4-02e8-43f9-a7f1-7db349e544ca'	System	08 Sep 2020 11:09:09
User entered '08 Sep 2020 07:09'	System	08 Sep 2020 11:09:09

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 7'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:26', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:33', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:35', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:41', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'None (0)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered 'No (N)'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-09-08T21:39:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a67810f-f404-46c5-a079-1d9af445e885'	System	09 Sep 2020 01:56:40
User entered '08 Sep 2020 21:39'	System	09 Sep 2020 01:56:40

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:26:03

US3542131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 14:35:54
User entered 'No (N)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:36
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:03:59

US3542131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:21:05
User entered '09 Sep 2020' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 14:35:54
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 17:04:36
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	17 Sep 2020 17:04:36
User entered empty; reason for change Data Entry Error	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:36
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 17:03:59
User entered '16 Sep 2020'	Madhu Balachandran (b) (4)	17 Sep 2020 17:03:59

US3542131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 14:35:54
User entered empty; reason for change Data Entry Error	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:36
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:03:59

US3542131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:21:05
User entered empty.	Madhu Balachandran (b) (4)	17 Sep 2020 17:03:59

US3542131

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:42

US3542131

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	17 Sep 2020 17:04:42

US3542131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:52

US3542131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered '16 Sep 2020'	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:52

US3542131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:52

US3542131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:21:05
User entered empty.	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:52

US3542131

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:21:05
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:04:55

US3542131

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	17 Sep 2020 17:04:55

US3542131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:26:34
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	24 Sep 2020 16:44:43

US3542131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:26:34
User entered '23 Sep 2020'	Madhu Balachandran (b) (4)	24 Sep 2020 16:44:43

US3542131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:26:34
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	24 Sep 2020 16:44:43

US3542131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:26:34
User entered empty.	Madhu Balachandran (b) (4)	24 Sep 2020 16:44:43

US3542131

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:26:34
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	24 Sep 2020 16:45:13

US3542131

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	24 Sep 2020 16:45:13

US3542131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:06

US3542131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:18:28
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:18:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '7 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:06

US3542131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:06

US3542131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'VISIT2'	System	08 Oct 2020 17:59:06

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:19:59
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:19:59
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '7 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '10:54'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '07 Oct 2020 10:54'	System	21 Jan 2021 19:19:59
User entered '7 Oct 2020 10:54'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '97.9' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '75'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'bpm'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'breaths/min'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '110'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '72'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	08 Oct 2020 18:01:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:32
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	08 Oct 2020 18:01:12
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:20:16
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:20:16
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '7 Oct 2020'	Erika Faust (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '12:06'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '07 Oct 2020 12:06'	System	21 Jan 2021 19:20:16
User entered '7 Oct 2020 12:06'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '98.0' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '80'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'bpm'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'breaths/min'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '108'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered '71'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	08 Oct 2020 18:01:12

US3542131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 04:05:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:38

US3542131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:20:24
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:20:24
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered '7 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:38

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	08 Oct 2020 03:03:33
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	08 Oct 2020 03:03:33
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	08 Oct 2020 03:03:33
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:03:33
User entered '07 Oct 2020'	(b) (4) Caroline Thoreson (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	08 Oct 2020 03:03:33
User entered '11:36'	Caroline Thoreson (b) (4) (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '07 Oct 2020 11:36'	System	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:03:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) Caroline Thoreson (b) (4)	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'ONCE'	System	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:07:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 15:38:57

US3542131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 04:05:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:47

US3542131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:20:36
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:20:36
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered '7 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:47

US3542131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered '11:00'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:47

US3542131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '07 Oct 2020 11:00'	System	21 Jan 2021 19:20:36
User entered '7 Oct 2020 11:00'	System	08 Oct 2020 17:59:47

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:13:21
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:20:44
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:20:44
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered '7 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 04:05:53
User entered '11:05'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '07 Oct 2020 11:05'	System	21 Jan 2021 19:20:44
User entered '7 Oct 2020 11:05'	System	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:05:53
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered empty.	System	08 Oct 2020 17:59:59

US3542131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	14 Oct 2020 04:05:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Oct 2020 17:58:38

US3542131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'I'	System	08 Oct 2020 17:58:38

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:55', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ea9794bb-d97c-40fe-a1db-0712ba82e77a'	System	07 Oct 2020 16:06:09
User entered 'Yes (Y)'	System	07 Oct 2020 16:06:09

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:06:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ea9794bb-d97c-40fe-a1db-0712ba82e77a'	System	07 Oct 2020 16:06:09
User entered '98.0'	System	07 Oct 2020 16:06:09

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:06:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ea9794bb-d97c-40fe-a1db-0712ba82e77a'	System	07 Oct 2020 16:06:09
User entered 'No (N)'	System	07 Oct 2020 16:06:09

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:06:06', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'ea9794bb-d97c-40fe-a1db-0712ba82e77a'	System	07 Oct 2020 16:06:09
User entered '07 Oct 2020 12:06'	System	07 Oct 2020 16:06:09

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 11:56'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:11', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb'	System	08 Oct 2020 03:16:06
User entered 'Yes (Y)'	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb' User entered '98.2'	System	08 Oct 2020 03:16:06
	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:21', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb'	System	08 Oct 2020 03:16:06
User entered 'Yes (Y)'	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
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 'Participant was contacted and medication was added to concomitant medication page.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 05:52:15
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).	Erika Faust (b) (4)	16 Oct 2020 18:19:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:30', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb'	(b) (4)	
User entered '1'	System	08 Oct 2020 03:16:06
	System	08 Oct 2020 03:16:06
	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:30', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb'	System	08 Oct 2020 03:16:06
User entered '0'	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:09:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'aede9a91-06a4-4d55-acbc-f386a071f6fb' User entered '07 Oct 2020 23:09'	System	08 Oct 2020 03:16:06
	System	08 Oct 2020 03:16:06

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 15:21'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 2'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:00:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	System	09 Oct 2020 03:01:19
User entered 'Yes (Y)'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:00:58', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	System	09 Oct 2020 03:01:19
User entered '98.4'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	System	09 Oct 2020 03:01:19
User entered 'Yes (Y)'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
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 'Participant was contacted and medication was added to concomitant medication page.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 05:52:20
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).	Erika Faust (b) (4)	16 Oct 2020 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	(b) (4)	
User entered '1'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	System	09 Oct 2020 03:01:19
User entered '0'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '428b2964-2f05-4422-b63b-292e1eb939b5'	System	09 Oct 2020 03:01:19
User entered '08 Oct 2020 23:01'	System	09 Oct 2020 03:01:19

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 3'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:27:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '476e9b5d-ef4a-49e1-9f8c-41a1ca85e0a5'	System	10 Oct 2020 03:27:57
User entered 'Yes (Y)'	System	10 Oct 2020 03:27:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:27:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '476e9b5d-ef4a-49e1-9f8c-41a1ca85e0a5'	System	10 Oct 2020 03:27:57
User entered '97.6'	System	10 Oct 2020 03:27:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:27:49', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '476e9b5d-ef4a-49e1-9f8c-41a1ca85e0a5'	System	10 Oct 2020 03:27:57
User entered 'No (N)'	System	10 Oct 2020 03:27:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:27:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '476e9b5d-ef4a-49e1-9f8c-41a1ca85e0a5'	System	10 Oct 2020 03:27:57
User entered '09 Oct 2020 23:27'	System	10 Oct 2020 03:27:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 4'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:27', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5dbb1c8e-2c56-44c4-bfac-3d3ffc30767d'	System	11 Oct 2020 02:02:40
User entered 'Yes (Y)'	System	11 Oct 2020 02:02:40

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5dbb1c8e-2c56-44c4-bfac-3d3ffc30767d'	System	11 Oct 2020 02:02:40
User entered '97.2'	System	11 Oct 2020 02:02:40

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:35', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5dbb1c8e-2c56-44c4-bfac-3d3ffc30767d'	System	11 Oct 2020 02:02:40
User entered 'No (N)'	System	11 Oct 2020 02:02:40

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:39', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5dbb1c8e-2c56-44c4-bfac-3d3ffc30767d'	System	11 Oct 2020 02:02:40
User entered '10 Oct 2020 22:02'	System	11 Oct 2020 02:02:40

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 5'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:03:59', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3d7c797d-8849-4004-a46e-5877605825a4'	System	12 Oct 2020 04:04:16
User entered 'Yes (Y)'	System	12 Oct 2020 04:04:16

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3d7c797d-8849-4004-a46e-5877605825a4' User entered '97.1'	System	12 Oct 2020 04:04:16
	System	12 Oct 2020 04:04:16

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:08', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3d7c797d-8849-4004-a46e-5877605825a4'	System	12 Oct 2020 04:04:16
User entered 'No (N)'	System	12 Oct 2020 04:04:16

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:11', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3d7c797d-8849-4004-a46e-5877605825a4'	System	12 Oct 2020 04:04:16
User entered '12 Oct 2020 00:04'	System	12 Oct 2020 04:04:16

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 6'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:50:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c1bb64b2-5af1-4930-b37f-3e59f91a8b2e'	System	13 Oct 2020 03:50:50
User entered 'Yes (Y)'	System	13 Oct 2020 03:50:50

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:50:40', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c1bb64b2-5af1-4930-b37f-3e59f91a8b2e'	System	13 Oct 2020 03:50:50
User entered '97.6'	System	13 Oct 2020 03:50:50

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:50:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c1bb64b2-5af1-4930-b37f-3e59f91a8b2e'	System	13 Oct 2020 03:50:50
User entered 'No (N)'	System	13 Oct 2020 03:50:50

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:50:48', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c1bb64b2-5af1-4930-b37f-3e59f91a8b2e'	System	13 Oct 2020 03:50:50
User entered '12 Oct 2020 23:50'	System	13 Oct 2020 03:50:50

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 7'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:12:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0747cf8d-ef3c-4eec-b54a-c23772fb4bb3'	System	14 Oct 2020 01:12:58
User entered 'Yes (Y)'	System	14 Oct 2020 01:12:58

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:12:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0747cf8d-ef3c-4eec-b54a-c23772fb4bb3'	System	14 Oct 2020 01:12:58
User entered '97.8'	System	14 Oct 2020 01:12:58

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:12:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0747cf8d-ef3c-4eec-b54a-c23772fb4bb3'	System	14 Oct 2020 01:12:58
User entered 'No (N)'	System	14 Oct 2020 01:12:58

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:12:57', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0747cf8d-ef3c-4eec-b54a-c23772fb4bb3'	System	14 Oct 2020 01:12:58
User entered '13 Oct 2020 21:12'	System	14 Oct 2020 01:12:58

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:04:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e39de6f3-a5a0-425e-95ae-b65cf163a22e'	System	07 Oct 2020 16:04:57
User entered 'None (1)'	System	07 Oct 2020 16:04:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:04:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e39de6f3-a5a0-425e-95ae-b65cf163a22e'	System	07 Oct 2020 16:04:57
User entered 'No (N)'	System	07 Oct 2020 16:04:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:04:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e39de6f3-a5a0-425e-95ae-b65cf163a22e'	System	07 Oct 2020 16:04:57
User entered 'No (N)'	System	07 Oct 2020 16:04:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:04:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e39de6f3-a5a0-425e-95ae-b65cf163a22e'	System	07 Oct 2020 16:04:57
User entered 'None (1)'	System	07 Oct 2020 16:04:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:04:55', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e39de6f3-a5a0-425e-95ae-b65cf163a22e'	System	07 Oct 2020 16:04:57
User entered '07 Oct 2020 12:04'	System	07 Oct 2020 16:04:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 11:56'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cf0c8b3d-de82-4058-ba50-ce2840b88219'	System	08 Oct 2020 03:17:08
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		08 Oct 2020 03:17:08

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cf0c8b3d-de82-4058-ba50-ce2840b88219'	System	08 Oct 2020 03:17:08
User entered 'No (N)'	System	08 Oct 2020 03:17:08

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cf0c8b3d-de82-4058-ba50-ce2840b88219'	System	08 Oct 2020 03:17:08
User entered 'No (N)'	System	08 Oct 2020 03:17:08

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cf0c8b3d-de82-4058-ba50-ce2840b88219'	System	08 Oct 2020 03:17:08
User entered 'None (1)'	System	08 Oct 2020 03:17:08

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:42', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cf0c8b3d-de82-4058-ba50-ce2840b88219'	System	08 Oct 2020 03:17:08
User entered '07 Oct 2020 23:10'	System	08 Oct 2020 03:17:08

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 15:21'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 2'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:27', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '984fd362-5678-41e2-a1be-4a6070d4a6c0'	System	09 Oct 2020 03:01:47
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		09 Oct 2020 03:01:47

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '984fd362-5678-41e2-a1be-4a6070d4a6c0'	System	09 Oct 2020 03:01:47
User entered 'No (N)'	System	09 Oct 2020 03:01:47

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '984fd362-5678-41e2-a1be-4a6070d4a6c0'	System	09 Oct 2020 03:01:47
User entered 'No (N)'	System	09 Oct 2020 03:01:47

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:40', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '984fd362-5678-41e2-a1be-4a6070d4a6c0'	System	09 Oct 2020 03:01:47
User entered 'None (1)'	System	09 Oct 2020 03:01:47

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:43', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '984fd362-5678-41e2-a1be-4a6070d4a6c0'	System	09 Oct 2020 03:01:47
User entered '08 Oct 2020 23:01'	System	09 Oct 2020 03:01:47

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 3'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fe9a1fa6-b339-48c5-a3d8-dfad28a0e571'	System	10 Oct 2020 03:28:23
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 03:28:23

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fe9a1fa6-b339-48c5-a3d8-dfad28a0e571'	System	10 Oct 2020 03:28:23
User entered 'No (N)'	System	10 Oct 2020 03:28:23

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:10', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fe9a1fa6-b339-48c5-a3d8-dfad28a0e571'	System	10 Oct 2020 03:28:23
User entered 'No (N)'	System	10 Oct 2020 03:28:23

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fe9a1fa6-b339-48c5-a3d8-dfad28a0e571'	System	10 Oct 2020 03:28:23
User entered 'None (1)'	System	10 Oct 2020 03:28:23

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fe9a1fa6-b339-48c5-a3d8-dfad28a0e571'	System	10 Oct 2020 03:28:23
User entered '09 Oct 2020 23:28'	System	10 Oct 2020 03:28:23

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 4'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e5402680-d862-4726-a203-c0ac2d23ded2'	System	11 Oct 2020 02:02:59
User entered 'None (1)'	System	11 Oct 2020 02:02:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:48', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e5402680-d862-4726-a203-c0ac2d23ded2'	System	11 Oct 2020 02:02:59
User entered 'No (N)'	System	11 Oct 2020 02:02:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e5402680-d862-4726-a203-c0ac2d23ded2'	System	11 Oct 2020 02:02:59
User entered 'No (N)'	System	11 Oct 2020 02:02:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e5402680-d862-4726-a203-c0ac2d23ded2'	System	11 Oct 2020 02:02:59
User entered 'None (1)'	System	11 Oct 2020 02:02:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:02:57', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e5402680-d862-4726-a203-c0ac2d23ded2'	System	11 Oct 2020 02:02:59
User entered '10 Oct 2020 22:02'	System	11 Oct 2020 02:02:59

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 5'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '50788e35-8ed8-449b-aebb-cbb3e8c7a8ac'	System	12 Oct 2020 04:04:30
User entered 'None (1)'	System	12 Oct 2020 04:04:30

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '50788e35-8ed8-449b-acbb-cbb3e8c7a8ac'	System	12 Oct 2020 04:04:30
User entered 'No (N)'	System	12 Oct 2020 04:04:30

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '50788e35-8ed8-449b-acbb-cbb3e8c7a8ac'	System	12 Oct 2020 04:04:30
User entered 'No (N)'	System	12 Oct 2020 04:04:30

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '50788e35-8ed8-449b-acbb-cbb3e8c7a8ac'	System	12 Oct 2020 04:04:30
User entered 'None (1)'	System	12 Oct 2020 04:04:30

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '50788e35-8ed8-449b-aebb-cbb3e8c7a8ac'	System	12 Oct 2020 04:04:30
User entered '12 Oct 2020 00:04'	System	12 Oct 2020 04:04:30

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 6'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:08', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'dfa84738-ab55-492a-ad19-5b6034d9e482'	System	13 Oct 2020 03:51:24
User entered 'None (1)'	System	13 Oct 2020 03:51:24

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'dfa84738-ab55-492a-ad19-5b6034d9e482'	System	13 Oct 2020 03:51:24
User entered 'No (N)'	System	13 Oct 2020 03:51:24

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:14', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'dfa84738-ab55-492a-ad19-5b6034d9e482'	System	13 Oct 2020 03:51:24
User entered 'No (N)'	System	13 Oct 2020 03:51:24

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:17', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'dfa84738-ab55-492a-ad19-5b6034d9e482'	System	13 Oct 2020 03:51:24
User entered 'None (1)'	System	13 Oct 2020 03:51:24

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:23', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'dfa84738-ab55-492a-ad19-5b6034d9e482'	System	13 Oct 2020 03:51:24
User entered '12 Oct 2020 23:51'	System	13 Oct 2020 03:51:24

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 7'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:02', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5152af49-f216-433b-b5ab-c030604ad29d'	System	14 Oct 2020 01:13:15
User entered 'None (1)'	System	14 Oct 2020 01:13:15

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:05', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5152af49-f216-433b-b5ab-c030604ad29d'	System	14 Oct 2020 01:13:15
User entered 'No (N)'	System	14 Oct 2020 01:13:15

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:08', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5152af49-f216-433b-b5ab-c030604ad29d'	System	14 Oct 2020 01:13:15
User entered 'No (N)'	System	14 Oct 2020 01:13:15

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5152af49-f216-433b-b5ab-c030604ad29d'	System	14 Oct 2020 01:13:15
User entered 'None (1)'	System	14 Oct 2020 01:13:15

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:14', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5152af49-f216-433b-b5ab-c030604ad29d'	System	14 Oct 2020 01:13:15
User entered '13 Oct 2020 21:13'	System	14 Oct 2020 01:13:15

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:04', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:14', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'None (0)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered 'No (N)'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T12:05:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3caa077d-7e17-4dc4-befa-3d53889f0d38'	System	07 Oct 2020 16:05:29
User entered '07 Oct 2020 12:05'	System	07 Oct 2020 16:05:29

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 11:56'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:55', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:10:58', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:11:01', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'None (0)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:11:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered 'No (N)'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-07T23:11:10', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '61dbc2b2-6352-4dd6-a8ad-a9faaa1ae37d'	System	08 Oct 2020 03:17:32
User entered '07 Oct 2020 23:11'	System	08 Oct 2020 03:17:32

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '07 Oct 2020 15:21'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 2'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:49', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:56', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:01:58', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:02:02', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'None (0)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:02:06', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered 'No (N)'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-08T23:02:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '31e40767-0028-4801-8673-69c02e7d6f59'	System	09 Oct 2020 03:02:14
User entered '08 Oct 2020 23:02'	System	09 Oct 2020 03:02:14

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 3'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:24', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:26', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:32', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'None (0)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:41', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered 'No (N)'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-09T23:28:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '99d97521-9538-484e-8dd7-f468d5bc2dd6'	System	10 Oct 2020 03:28:46
User entered '09 Oct 2020 23:28'	System	10 Oct 2020 03:28:46

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 4'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:01', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:05', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:07', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'None (0)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered 'No (N)'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-10T22:03:18', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '874156b7-d0aa-41ec-ad31-f119df19b08a'	System	11 Oct 2020 02:03:22
User entered '10 Oct 2020 22:03'	System	11 Oct 2020 02:03:22

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 5'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:33', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:39', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:42', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:46', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'None (0)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered 'No (N)'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T00:04:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '0230261a-9590-44ab-b26b-6070ed28fe6c'	System	12 Oct 2020 04:04:55
User entered '12 Oct 2020 00:04'	System	12 Oct 2020 04:04:55

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 6'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:27', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:32', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:37', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:40', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'None (0)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:44', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered 'No (N)'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-12T23:51:47', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b88d104a-3505-463e-8dc7-7594e7c4a9a9'	System	13 Oct 2020 03:51:50
User entered '12 Oct 2020 23:51'	System	13 Oct 2020 03:51:50

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	07 Oct 2020 15:38:57
User entered 'Day 7'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:18', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:22', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:27', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:29', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'None (0)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:33', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered 'No (N)'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-10-13T21:13:35', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '220ed391-ba35-4ca6-8f75-eab0726de12c'	System	14 Oct 2020 01:13:39
User entered '13 Oct 2020 21:13'	System	14 Oct 2020 01:13:39

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:38:57

US3542131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:07:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:38:57

US3542131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Oct 2020 16:34:11

US3542131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '14 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Oct 2020 16:34:11

US3542131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Oct 2020 16:34:11

US3542131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Erika Faust (b) (4)	15 Oct 2020 16:34:11

US3542131

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 02:57:27
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Oct 2020 16:34:18

US3542131

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	15 Oct 2020 16:34:18

US3542131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:53:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 17:34:00

US3542131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:53:05
User entered '21 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 17:34:00
	(b) (4)	

US3542131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:53:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 17:34:00

US3542131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:53:05
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 17:34:00

US3542131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:53:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 17:34:04

US3542131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	22 Oct 2020 17:34:04

US3542131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Oct 2020 18:23:38

US3542131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:22:41
User entered '28 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	29 Oct 2020 18:23:38

US3542131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	29 Oct 2020 18:23:38

US3542131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:22:41
User entered empty.	(b) (4) Erika Faust (b) (4)	29 Oct 2020 18:23:38

US3542131

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:22:41
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	29 Oct 2020 18:23:43

US3542131

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	29 Oct 2020 18:23:43

US3542131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 21:51:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:39:56

US3542131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:39:56

US3542131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 21:51:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 16:39:56

US3542131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'VISIT3'	System	05 Nov 2020 16:39:56

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:24
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:19:47
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly.	Erika Faust (b) (4)	13 Nov 2020 14:21:06
' answered with 'Date updated' (Site from DM).	(b) (4)	
User entered '04 Nov 2020' reason for change: Per Query Resolution	Erika Faust (b) (4)	13 Nov 2020 14:21:00
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:58:49
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '10:52'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '04 Nov 2020 10:52'	System	13 Nov 2020 14:21:00
User entered '4 Nov 2020 10:52'	System	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:24
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '78'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'bpm'	System	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '15'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'breaths/min'	System	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '119'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '71'	(b) (4), (b) (6)	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'mmHg'	System	05 Nov 2020 16:40:46

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02

US3542131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02

US3542131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 21:51:49
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:41:20

US3542131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 21:51:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:41:20

US3542131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:41:38

US3542131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 04NOV2020. However, collection date is missing in GCL. Please confirm if 04NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:09:46
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:24
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 04NOV2020. However, collection date is missing in GCL. Please confirm if 04NOV2020 is correct date to update in GCL records. ' answered with '04Nov2020 is the correct date.' (Site from DM).	Hannah Yellin (b) (4)	18 Nov 2020 14:48:53
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 04NOV2020. However, collection date is missing in GCL. Please confirm if 04NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:03:52
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 16:41:38

US3542131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	20 Nov 2020 04:15:24
User entered '11:04'	(b) (4), (b) (6)	05 Nov 2020 16:41:38

US3542131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered '4 Nov 2020 11:04'	System	05 Nov 2020 16:41:38

US3542131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4) (b) (4)	12 Nov 2020 21:51:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:41:47

US3542131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	05 Nov 2020 16:41:47

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 64'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Please 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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Please 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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Please 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)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:45:17
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 71'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-13T13:35:20', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c5625eb4-23e0-4450-bd06-b719644291f4'	System	13 Nov 2020 18:35:33
User entered 'No (N)'	System	13 Nov 2020 18:35:33

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-13T13:35:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c5625eb4-23e0-4450-bd06-b719644291f4'	System	13 Nov 2020 18:35:33
User entered 'No (N)'	System	13 Nov 2020 18:35:33

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-13T13:35:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c5625eb4-23e0-4450-bd06-b719644291f4' User entered '13 Nov 2020 13:35:31'	System	13 Nov 2020 18:35:33
	System	13 Nov 2020 18:35:33

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered 'Day 78'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-19T06:32:01', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e2db6622-dd93-4473-aa2d-432f0532670c'	System	19 Nov 2020 14:32:18
User entered 'No (N)'	System	19 Nov 2020 14:32:18

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-19T06:32:09', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e2db6622-dd93-4473-aa2d-432f0532670c'	System	19 Nov 2020 14:32:18
User entered 'No (N)'	System	19 Nov 2020 14:32:18

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-19T06:32:15', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e2db6622-dd93-4473-aa2d-432f0532670c' User entered '19 Nov 2020 06:32:15'	System	19 Nov 2020 14:32:18
	System	19 Nov 2020 14:32:18

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 18:26:03

US3542131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:00:38
Data entry locked.	System	02 Sep 2020 18:26:03
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 18:26:03

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2020-11-28T13:20:13', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5da701bd-91ad-4d17-b581-835977ab5c6c'	System	28 Nov 2020 21:20:26
User entered 'No (N)'	System	28 Nov 2020 21:20:26

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2020-11-28T13:20:19', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5da701bd-91ad-4d17-b581-835977ab5c6c'	System	28 Nov 2020 21:20:26
User entered 'No (N)'	System	28 Nov 2020 21:20:26

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-11-28T13:20:25', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5da701bd-91ad-4d17-b581-835977ab5c6c'	System	28 Nov 2020 21:20:26
User entered '28 Nov 2020 13:20:25'	System	28 Nov 2020 21:20:26

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2020-12-07T14:43:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e52436f-2d51-4984-ba57-60d564c482fa'	System	07 Dec 2020 22:43:13
User entered 'No (N)'	System	07 Dec 2020 22:43:13

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2020-12-07T14:43:06', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e52436f-2d51-4984-ba57-60d564c482fa'	System	07 Dec 2020 22:43:13
User entered 'No (N)'	System	07 Dec 2020 22:43:13

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-12-07T14:43:11', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '4e52436f-2d51-4984-ba57-60d564c482fa' User entered '07 Dec 2020 14:43:11'	System	07 Dec 2020 22:43:13
	System	07 Dec 2020 22:43:13

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2020-12-13T09:20:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cd5a4606-5f66-449b-b33e-d3883e717bfc'	System	13 Dec 2020 17:21:06
User entered 'No (N)'	System	13 Dec 2020 17:21:06

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2020-12-13T09:20:55', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cd5a4606-5f66-449b-b33e-d3883e717bfc'	System	13 Dec 2020 17:21:06
User entered 'No (N)'	System	13 Dec 2020 17:21:06

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-12-13T09:21:02', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'cd5a4606-5f66-449b-b33e-d3883e717bfc'	System	13 Dec 2020 17:21:06
User entered '13 Dec 2020 09:21:02'	System	13 Dec 2020 17:21:06

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2020-12-19T07:13:03', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fb5be105-3dae-410a-915f-5f2e0d44d901'	System	19 Dec 2020 15:13:16
User entered 'No (N)'	System	19 Dec 2020 15:13:16

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2020-12-19T07:13:10', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fb5be105-3dae-410a-915f-5f2e0d44d901'	System	19 Dec 2020 15:13:16
User entered 'No (N)'	System	19 Dec 2020 15:13:16

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-12-19T07:13:16', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'fb5be105-3dae-410a-915f-5f2e0d44d901'	System	19 Dec 2020 15:13:16
User entered '19 Dec 2020 07:13:16'	System	19 Dec 2020 15:13:16

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2020-12-29T16:19:05', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '97aa7086-b027-412d-ab06-2fb6a775c96d'	System	30 Dec 2020 00:19:18
User entered 'No (N)'	System	30 Dec 2020 00:19:18

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2020-12-29T16:19:12', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '97aa7086-b027-412d-ab06-2fb6a775c96d'	System	30 Dec 2020 00:19:18
User entered 'No (N)'	System	30 Dec 2020 00:19:18

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2020-12-29T16:19:18', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '97aa7086-b027-412d-ab06-2fb6a775c96d' User entered '29 Dec 2020 16:19:18'	System	30 Dec 2020 00:19:18

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-01-05T15:39:34', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '1772844e-0aff-4d2c-b8c0-9279e1f0d597'	System	05 Jan 2021 23:39:46
User entered 'No (N)'	System	05 Jan 2021 23:39:46

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-01-05T15:39:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '1772844e-0aff-4d2c-b8c0-9279e1f0d597'	System	05 Jan 2021 23:39:46
User entered 'No (N)'	System	05 Jan 2021 23:39:46

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-01-05T15:39:42', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '1772844e-0aff-4d2c-b8c0-9279e1f0d597'	System	05 Jan 2021 23:39:46
User entered '05 Jan 2021 15:39:42'	System	05 Jan 2021 23:39:46

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-01-10T21:24:32', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a59338a-4a79-4459-b6a6-45d5c2887d73'	System	11 Jan 2021 02:24:47
User entered 'No (N)'	System	11 Jan 2021 02:24:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-01-10T21:24:38', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a59338a-4a79-4459-b6a6-45d5c2887d73'	System	11 Jan 2021 02:24:47
User entered 'No (N)'	System	11 Jan 2021 02:24:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-01-10T21:24:45', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '6a59338a-4a79-4459-b6a6-45d5c2887d73'	System	11 Jan 2021 02:24:47
User entered '10 Jan 2021 21:24:45'	System	11 Jan 2021 02:24:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-01-19T10:06:05', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8b3eca6e-203c-44fc-9166-61b1f02e0fdb'	System	19 Jan 2021 15:06:14
User entered 'No (N)'	System	19 Jan 2021 15:06:14

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-01-19T10:06:10', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8b3eca6e-203c-44fc-9166-61b1f02e0fdb'	System	19 Jan 2021 15:06:14
User entered 'No (N)'	System	19 Jan 2021 15:06:14

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-01-19T10:06:13', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8b3eca6e-203c-44fc-9166-61b1f02e0fdb' User entered '19 Jan 2021 10:06:13'	System	19 Jan 2021 15:06:14

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-01-25T08:50:51', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5b43ab9b-1adc-433f-8225-9985e91d030e'	System	25 Jan 2021 13:51:01
User entered 'No (N)'	System	25 Jan 2021 13:51:01

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-01-25T08:50:54', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5b43ab9b-1adc-433f-8225-9985e91d030e'	System	25 Jan 2021 13:51:01
User entered 'No (N)'	System	25 Jan 2021 13:51:01

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-01-25T08:50:58', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5b43ab9b-1adc-433f-8225-9985e91d030e'	System	25 Jan 2021 13:51:01
User entered '25 Jan 2021 08:50:58'	System	25 Jan 2021 13:51:01

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-01-29T23:06:46', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c834ead8-a0d3-4596-bf62-adfb388e23c3'	System	30 Jan 2021 04:06:58
User entered 'No (N)'	System	30 Jan 2021 04:06:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-01-29T23:06:50', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c834ead8-a0d3-4596-bf62-adfb388e23c3'	System	30 Jan 2021 04:06:58
User entered 'No (N)'	System	30 Jan 2021 04:06:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-01-29T23:06:53', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c834ead8-a0d3-4596-bf62-adfb388e23c3' User entered '29 Jan 2021 23:06:53'	System	30 Jan 2021 04:06:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-02-07T16:00:24', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3840b7ea-9b42-4c61-9c4b-21ee14e8145d'	System	07 Feb 2021 21:00:36
User entered 'No (N)'	System	07 Feb 2021 21:00:36

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-02-07T16:00:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3840b7ea-9b42-4c61-9c4b-21ee14e8145d'	System	07 Feb 2021 21:00:36
User entered 'No (N)'	System	07 Feb 2021 21:00:36

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-02-07T16:00:31', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3840b7ea-9b42-4c61-9c4b-21ee14e8145d'	System	07 Feb 2021 21:00:36
User entered '07 Feb 2021 16:00:31'	System	07 Feb 2021 21:00:36

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-02-22T15:20:18', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '781472da-0a3b-4b10-a47f-b971439f6ca3'	System	22 Feb 2021 20:20:31
User entered 'No (N)'	System	22 Feb 2021 20:20:31

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-02-22T15:20:24', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '781472da-0a3b-4b10-a47f-b971439f6ca3'	System	22 Feb 2021 20:20:31
User entered 'No (N)'	System	22 Feb 2021 20:20:31

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-02-22T15:20:28', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '781472da-0a3b-4b10-a47f-b971439f6ca3'	System	22 Feb 2021 20:20:31
User entered '22 Feb 2021 15:20:28'	System	22 Feb 2021 20:20:31

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-02-28T08:05:43-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '006494a3-e282-426b-adb0-548a17047fce' User entered 'No (N)'	System	28 Feb 2021 13:05:58
	System	28 Feb 2021 13:05:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-02-28T08:05:47-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '006494a3-e282-426b-adb0-548a17047fce' User entered 'No (N)'	System	28 Feb 2021 13:05:58
	System	28 Feb 2021 13:05:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-02-28T08:05:55-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '006494a3-e282-426b-adb0-548a17047fce' User entered '28 Feb 2021 08:05:55'	System	28 Feb 2021 13:05:58
	System	28 Feb 2021 13:05:58

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-03-05T08:37:49-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '52dac7d9-0d60-4f98-8d4b-5d58d4562852'	System	05 Mar 2021 13:38:03
User entered 'No (N)'	System	05 Mar 2021 13:38:03

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-03-05T08:37:53-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '52dac7d9-0d60-4f98-8d4b-5d58d4562852'	System	05 Mar 2021 13:38:03
User entered 'No (N)'	System	05 Mar 2021 13:38:03

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-03-05T08:37:57-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '52dac7d9-0d60-4f98-8d4b-5d58d4562852'	System	05 Mar 2021 13:38:03
User entered '05 Mar 2021 08:37:57'	System	05 Mar 2021 13:38:03

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-03-23T08:07:33-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c4c1133a-ca4c-4dfe-8b50-78ac18ef26fc'	System	23 Mar 2021 12:07:47
User entered 'No (N)'	System	23 Mar 2021 12:07:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-03-23T08:07:38-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c4c1133a-ca4c-4dfe-8b50-78ac18ef26fc'	System	23 Mar 2021 12:07:47
User entered 'No (N)'	System	23 Mar 2021 12:07:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-03-23T08:07:44-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'c4c1133a-ca4c-4dfe-8b50-78ac18ef26fc' User entered '23 Mar 2021 08:07:44'	System	23 Mar 2021 12:07:47
	System	23 Mar 2021 12:07:47

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-05T20:57:01-07:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e89d773a-6f53-4476-9220-957ae458709d'	System	06 Apr 2021 03:57:10
User entered 'No (N)'	System	06 Apr 2021 03:57:10

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-04-05T20:57:06-07:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e89d773a-6f53-4476-9220-957ae458709d'	System	06 Apr 2021 03:57:10
User entered 'No (N)'	System	06 Apr 2021 03:57:10

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-04-05T20:57:10-07:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'e89d773a-6f53-4476-9220-957ae458709d' User entered '05 Apr 2021 20:57:10'	System	06 Apr 2021 03:57:10
	System	06 Apr 2021 03:57:10

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-09T16:00:46-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1' User entered 'Yes (Y)'	System	09 Apr 2021 20:01:52
	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-04-09T16:00:52-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1' User entered 'No (N)'	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-09T16:00:59-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1'	System	09 Apr 2021 20:01:52
User entered 'No (N)'	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-09T16:01:08-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1'	System	09 Apr 2021 20:01:52
User entered 'Yes (Y)'	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Please 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 (ff4e0864906b9975)', Time: '2021-04-09T16:01:24-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1'	System	09 Apr 2021 20:01:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-04-09T16:01:34-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '5cb392d4-43e4-4faf-ad91-f418b55e55a1' User entered '09 Apr 2021 16:01:34'	System	09 Apr 2021 20:01:52
	System	09 Apr 2021 20:01:52

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-17T17:52:18-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8ca8e6e8-0566-46a5-a200-27f673014ba0'	System	17 Apr 2021 21:53:05
User entered 'Yes (Y)'	System	17 Apr 2021 21:53:05

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-04-17T17:52:24-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8ca8e6e8-0566-46a5-a200-27f673014ba0'	System	17 Apr 2021 21:53:05
User entered 'No (N)'	System	17 Apr 2021 21:53:05

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-17T17:52:31-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8ca8e6e8-0566-46a5-a200-27f673014ba0'	System	17 Apr 2021 21:53:05
User entered 'No (N)'	System	17 Apr 2021 21:53:05

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-17T17:52:48-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8ca8e6e8-0566-46a5-a200-27f673014ba0'	System	17 Apr 2021 21:53:05
User entered 'No (N)'	System	17 Apr 2021 21:53:05

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-04-17T17:53:01-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '8ca8e6e8-0566-46a5-a200-27f673014ba0'	System	17 Apr 2021 21:53:05
User entered '17 Apr 2021 17:53:01'	System	17 Apr 2021 21:53:05

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-04-23T20:33:29-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '329811fb-91e8-4ee7-ae69-770b3bc3facc'	System	24 Apr 2021 00:33:41
User entered 'No (N)'	System	24 Apr 2021 00:33:41

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-04-23T20:33:35-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '329811fb-91e8-4ee7-ae69-770b3bc3facc'	System	24 Apr 2021 00:33:41
User entered 'No (N)'	System	24 Apr 2021 00:33:41

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-04-23T20:33:39-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '329811fb-91e8-4ee7-ae69-770b3bc3facc'	System	24 Apr 2021 00:33:41
User entered '23 Apr 2021 20:33:39'	System	24 Apr 2021 00:33:41

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[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 (ff4e0864906b9975)', Time: '2021-05-01T07:56:01-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b6a0a7d2-9c37-4e58-97a8-cdbd8317cc29'	System	01 May 2021 11:56:12
User entered 'No (N)'	System	01 May 2021 11:56:12

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Have you been exposed to someone with 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 (ff4e0864906b9975)', Time: '2021-05-01T07:56:05-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b6a0a7d2-9c37-4e58-97a8-cdbd8317cc29'	System	01 May 2021 11:56:12
User entered 'No (N)'	System	01 May 2021 11:56:12

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-05-01T07:56:09-04:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: 'b6a0a7d2-9c37-4e58-97a8-cdbd8317cc29'	System	01 May 2021 11:56:12
User entered '01 May 2021 07:56:09'	System	01 May 2021 11:56:12

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:45:17

US3542131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:07:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:45:17
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:45:17

US3542131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:07:20

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)	24 Apr 2021 15:58:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-02-28T08:05:29-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3818983d-e334-484b-9284-572bf083260d'	System	28 Feb 2021 13:05:35
User entered 'No (N)'	System	28 Feb 2021 13:05:35

US3542131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:07:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ff4e0864906b9975)', Time: '2021-02-28T08:05:33-05:00', User OID: 'PatientReportedOutcome (US3542131)', ODM File OID: '3818983d-e334-484b-9284-572bf083260d' User entered '28 Feb 2021 08:05:33'	System	28 Feb 2021 13:05:35
	System	28 Feb 2021 13:05:35

US3542131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:08:18
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:00:11

US3542131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:18
User entered '02 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:00:11

US3542131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:08:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:00:11

US3542131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:08:18
User entered empty.	(b) (4) Erika Faust (b) (4)	03 Dec 2020 17:00:11

US3542131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User signature succeeded.	David Diemert (u) (4)	10 Dec 2020 16:08:18
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Dec 2020 17:00:19

US3542131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:10:02
User entered 'l'	System	03 Dec 2020 17:00:19

US3542131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:43:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:39:29

US3542131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:43:27
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:39:29

US3542131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:43:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 14:39:29

US3542131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:43:27
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 14:39:29

US3542131

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:43:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:39:36

US3542131

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User entered 'l'	System	11 Jan 2021 14:39:36

US3542131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Feb 2021 18:59:18

US3542131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
User entered '03 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Feb 2021 18:59:18

US3542131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	04 Feb 2021 18:59:18

US3542131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
User entered empty.	(b) (4) Erika Faust (b) (4)	04 Feb 2021 18:59:18

US3542131

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Feb 2021 18:59:23

US3542131

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User entered 'l'	System	04 Feb 2021 18:59:23

US3542131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 14:56:54
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	03 Mar 2021 20:06:08

US3542131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 14:56:54
User entered '03 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	03 Mar 2021 20:06:08
	(b) (4)	

US3542131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 14:56:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	03 Mar 2021 20:06:08

US3542131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:07:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 14:56:54
User entered empty.	(b) (4) Taylor Ladson (b) (4)	03 Mar 2021 20:06:08
	(b) (4)	

US3542131

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 14:56:54
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	03 Mar 2021 20:05:59

US3542131

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:28:12
User entered 'l'	System	03 Mar 2021 20:05:59

US3542131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:11:59

US3542131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:11:59

US3542131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:11:59

US3542131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 17:11:59

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:07:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:12:18

US3542131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:28

US3542131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:07:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:12:28

US3542131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:13:45

US3542131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:13:45

US3542131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '14:41'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:13:45

US3542131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 14:41'	System	13 Apr 2021 17:13:45

US3542131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:14:23

US3542131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:07:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:14:23

US3542131

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

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:42:45

US3542131

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

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '25 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:42:45

US3542131

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

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[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 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'Clinic (Clinic)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:42:45

US3542131

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

Form: Visit Date

Generated On: 10 Jun 2021 08:07:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 15:42:45

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '25 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:44:08
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:02:10

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:44:08
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:02:10

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '25 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Hannah Yellin (b) (4)	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Hannah Yellin (b) (4)	26 Jan 2021 15:43:07
	(b) (4)	

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Hannah Yellin (b) (4)	26 Jan 2021 15:43:07
	(b) (4)	

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	26 Jan 2021 15:43:07

US3542131

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

Form: Unblinding

Generated On: 10 Jun 2021 08:07:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered empty.	System	26 Jan 2021 15:43:07

US3542131

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:29

US3542131

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '25 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:29

US3542131

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '14:03'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:29

US3542131

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '25 Jan 2021 14:03'	System	26 Jan 2021 15:43:29

US3542131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:42

US3542131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '25 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:42

US3542131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User entered '14:10'	(b) (4) Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 15:43:42

US3542131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:34
User entered '25 Jan 2021 14:10'	System	26 Jan 2021 15:43:42

US3542131

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:07:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:02
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	12 Apr 2021 19:10:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Caroline Thoreson (b) (4)	12 Apr 2021 19:10:15
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:35:16
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	03 Feb 2021 19:45:19
	(b) (4)	

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:04
User entered 'USA-US084-2021-mRNA-1273-P301000009'	System	13 Apr 2021 19:00:58
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 19:00:58

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User closed query 'PV Query: Please update the event verbatim with the final diagnosis of the event, when available. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:47:54
Query 'PV Query: Please update the event verbatim with the final diagnosis of the event, when available. ' answered with 'Done.' (Site from Safety).	David Diemert (b) (4)	22 Apr 2021 13:31:36
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Ileus, LLT: Ileus - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 13:30:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 13:30:27
Data point term sent to Coder	System	21 Apr 2021 13:28:41
Coding entries removed.	David Diemert (b) (4)	21 Apr 2021 13:28:04
Signature has been broken.	David Diemert (b) (4)	21 Apr 2021 13:28:04
User entered 'Ileus' reason for change: New Information	David Diemert (b) (4)	21 Apr 2021 13:28:04
User opened query 'PV Query: Please update the event verbatim with the final diagnosis of the event, when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:08:57
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Right upper quadrant pain - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:35
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
Data point term sent to Coder	System	12 Apr 2021 19:13:17
User entered 'Right upper quadrant abdominal pain'	Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '5 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:48:20
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Provided' (Site from Safety).	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:52:57
Signature has been broken.	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:52:25
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:52:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:08:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Apr 2021 20:34:10
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 03:41:44
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Updated' (Site from System).	David Diemert (b) (4)	22 Apr 2021 13:53:30
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Apr 2021 13:52:25
Signature has been broken.	David Diemert (b) (4)	22 Apr 2021 13:52:25
User entered '10 Apr 2021' reason for change: New Information	David Diemert (b) (4)	22 Apr 2021 13:52:25
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered empty.	Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '8 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '10 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04
	(b) (4)	

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'l'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:48:35
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'Updated' (Site from Safety).	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:55:49
Signature has been broken.	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:54:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:54:13
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:08:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Apr 2021 19:57:43
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 17:21:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 17:21:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Apr 2021 20:34:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Caroline Thoreson (b) (4) (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:48:28
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:48:07
User closed query 'PV Query: Please provide the use of other concomitant products, particularly the narcotics use. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:47:34
Query 'PV Query: Please provide the use of other concomitant products, particularly the narcotics use. ' answered with 'Added to narrative and con med log.' (Site from Safety).	David Diemert (b) (4)	22 Apr 2021 13:57:39
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Participant is s/p colectomy with an ileostomy (h/o ulcerative colitis), as described in narrative.' (Site from Safety).	David Diemert (b) (4)	22 Apr 2021 13:57:19
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 'There is no record of COVID-19 testing during admission. ' (Site from Safety).	David Diemert (b) (4)	22 Apr 2021 13:56:31

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH PMH OF ULCERATIVE COLITIS (S/P TOTAL COLECTOMY AND ILEOSTOMY) STARTED EXPERIENCING RUQ ABDOMINAL PAIN ON 5-APR-21. PT PRESENTED TO URGENT CARE ON 8-APR-21 AND WAS OBSERVED FOR TWO NIGHTS ON THEIR OBSERVATION/URGENT CARE UNIT. PARTICIPANT WAS DISCHARGED HOME ON 10-APR-21. CT (ABDOMEN) WAS PERFORMED on 09APR2021 that showed s/p colectomy with RLQ ileostomy, and diffusely prominent loops of small bowel with air-fluid levels suggestive of ileus. Was managed conservatively with IV hydration and IV dilaudid (despite dx of possible ileus). Pain resolved and gas and stool visualized in osteomy bag on 10APR2021. Plain film KUB on evening of 9APR2021 showed normal bowel gas pattern and no evidence of ileus, so was discharged home the following day.' reason for change: New Information Signature has been broken.	David Diemert (b) (4) (b) (4)	22 Apr 2021 13:51:35
	David Diemert (b) (4) (b) (4)	21 Apr 2021 13:29:56
User entered 'PT WITH PMH OF ULCERATIVE COLITIS (S/P total colectomy and ILEOSTOMY) STARTED EXPERIENCING RUQ ABDOMINAL PAIN ON 5-APR-21. PT PRESENTED TO URGENT CARE ON 8-APR-21 AND WAS OBSERVED FOR TWO NIGHTS ON THEIR OBSERVATION/URGENT CARE UNIT. PARTICIPANT WAS discharged HOME ON 10-APR-21. PARTICIPANT REPORTS LABS AND CT (ABDOMEN) WAS PERFORMED WHICH DID NOT SHOW ANY CONCRETE DIAGNOSIS/ETIOLOGY OF PAIN. PARTICIPANT IS TAKING DILAUDID FOR PAIN.' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	21 Apr 2021 13:29:56
User opened query 'PV Query: Please provide the use of other concomitant products, particularly the narcotics use. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:09:06
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:08:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:06:13
User signature succeeded.	David Diemert (b) (4)	12 Apr 2021 20:34:10
User entered 'Pt with PMH of ulcerative colitis (s/p ileostomy) started experiencing RUQ abdominal pain on 5-APR-21. Pt presented to Urgent Care on 8-APR-21 and was observed for two nights on their observation/urgent care unit. Participant was sent home on 10-APR-21. Participant reports labs and CT (Abdomen) was performed which did not show any concrete diagnosis/etiology of pain. Participant is taking dilaudid for pain.'	(b) (4) Caroline Thoreson (b) (4)	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:13:04

US3542131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:07:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 19:13:04

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:07:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:02
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:06:46

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: GEMFIBROZIL, PRODUCTSYNONYM: LOPID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:08:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:08:51
Data point term sent to Coder	System	03 Sep 2020 19:08:07
User entered 'Lopid'	Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Elevated Triglycerides'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '300'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'twice daily (BID)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'UN UNK 2000'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:42:50
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:07:25

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 19:11:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 19:11:52
Data point term sent to Coder	System	10 Sep 2020 19:11:04
User entered 'Tylenol'	Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'Injection Site Pain'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '650'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'twice daily (BID)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '02 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered '02 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 05:00:46
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User entered '2'	System	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User entered 'I'	System	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:28
User entered '804 (804)'	System	10 Sep 2020 19:10:35

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:07:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:07:33
Data point term sent to Coder	System	15 Oct 2020 15:48:48
User entered 'tylenol'	Taylor Ladson (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:31:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	David Diemert (b) (4) (b) (4)	22 Dec 2020 22:36:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Dec 2020 20:43:06
	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'injection site pain'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 09:08:06
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	David Diemert (b) (4) (b) (4)	27 Jan 2021 14:47:31
Signature has been broken.	David Diemert (b) (4) (b) (4)	27 Jan 2021 14:47:22
User entered '975' reason for change: New Information	David Diemert (b) (4) (b) (4)	27 Jan 2021 14:47:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 20:42:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:57:27
User entered '3'	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
Signature has been broken.	David Diemert (b) (4)	27 Jan 2021 14:47:22
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	27 Jan 2021 14:47:22
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'tablet (TABLET)'	Taylor Ladson (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13
	(b) (4)	

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13
	(b) (4)	

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:16:28
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:16:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '7 Oct 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13
	(b) (4)	

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:20:27
Signature has been broken.	(b) (4), (b) (6)	21 Jan 2021 19:16:28
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 19:16:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered '8 Oct 2020'	Taylor Ladson (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:57:27
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User entered 'I'	System	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User entered 'I'	System	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:15
User entered '804 (804)'	System	15 Oct 2020 15:48:13

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:45:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:45:20
Data point term sent to Coder	System	05 Nov 2020 16:44:32
User entered 'Influenza Vaccination'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'Flu prevention'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '0.5'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:51:49
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User entered empty.	System	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User entered empty.	System	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:01:22
User entered empty.	System	05 Nov 2020 16:43:56

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Apr 2021 17:57:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 17:57:10
Data point term sent to Coder	System	13 Apr 2021 17:26:47
User entered 'Dilaudid'	(b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Right Upper Quadrant abdominal pain'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 17:26:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:14:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Apr 2021 20:28:28
Data point term sent to Coder	System	22 Apr 2021 17:18:27
User entered 'Ketorolac'	Taylor Ladson (b) (4) (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'RUQ Abdominal pain'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '30'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '08 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '09 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 17:17:45

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:24:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:24:37
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
Data point term sent to Coder	System	22 Apr 2021 17:18:33
User entered 'Hydromorphone (Dilaudid)'	Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'RUQ Abdominal pain'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '.5'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '08 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '10 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:07:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 17:18:20

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:07:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:02
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
DataPoint Un-verified.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:14:23
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:14:23
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:02:51
User closed query 'Per ETRTR: Abdomen CT is mentioned within narrative for SAE "Right Upper Quadrant Abdominal Pain". Please consider adding in this folder and updating SAE page to tick on "Concomitant Procedures" action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:02:38
Query 'Per ETRTR: Abdomen CT is mentioned within narrative for SAE "Right Upper Quadrant Abdominal Pain". Please consider adding in this folder and updating SAE page to tick on "Concomitant Procedures" action taken, thanks.' answered with 'A CT is not a procedure, it is a diagnostic exam.' (Site from CRA).	David Diemert (b) (4) (b) (4)	15 Apr 2021 02:42:13
User opened query 'Per ETRTR: Abdomen CT is mentioned within narrative for SAE "Right Upper Quadrant Abdominal Pain". Please consider adding in this folder and updating SAE page to tick on "Concomitant Procedures" action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:19:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	04 Feb 2021 22:35:16
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	03 Feb 2021 19:45:10

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:07:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '09 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:15:05

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:07:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'X-ray Abdomen'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:15:05

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Adverse Event (AE)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:15:05

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:07:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:15:05

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:07:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '09 Apr 2021'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:16:45

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:07:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'CT abdomen/ P/e pelvis with contrast'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:16:45

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:07:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'Adverse Event (AE)'	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:16:45

US3542131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:07:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Apr 2021 17:16:45

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'USA-US084-2021-MRNA-1273-P301000009'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'David'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Diemert'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '2300 Eye Street NW'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Washington'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '20037'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'US'	(b) (4) System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 18:41:25
User entered '2'	System	22 Apr 2021 13:30:15
User entered '1'	System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'USA-US084-2021-MRNA-1273-P301000009'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'David'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Diemert'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '2300 Eye Street NW'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Washington'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '20037'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'US'	(b) (4) System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 18:41:25
User entered '2'	System	22 Apr 2021 13:30:15
User entered '1'	System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:07:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '13/Apr/2021 12:02'	(b) (4) System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:07:20

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.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:22
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 19:02:13

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'USA-US084-2021-MRNA-1273-P301000009'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'David'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Diemert'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '2300 Eye Street NW'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Washington'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '20037'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'US'	(b) (4) System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 18:41:25
User entered '2'	System	22 Apr 2021 13:30:15
User entered '1'	System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:07:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 15:12:57
User entered '22/Apr/2021 06:30'	(b) (4) System	22 Apr 2021 13:30:15

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:07:20

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.	David Diemert (b) (4)	22 Apr 2021 15:12:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:30:15

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'USA-US084-2021-MRNA-1273-P301000009'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Yes (Y)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'No (N)'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'David'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Diemert'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '2300 Eye Street NW'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered 'Washington'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:01:47
User entered '20037'	System	13 Apr 2021 19:00:58

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:43
User entered 'US'	(b) (4) System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:07:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 18:41:25
User entered '2'	System	22 Apr 2021 13:30:15
User entered '1'	System	13 Apr 2021 19:02:22

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:07:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered '22/Apr/2021 14:41'	(b) (4) System	22 Apr 2021 18:41:25

US3542131

Folder: SAE USA-US084-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:07:20

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.	David Diemert (b) (4)	22 Apr 2021 20:28:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:41:25