

US3412262 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:35:47

All time stamps listed in this document are displayed in GMT

US3412262

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:57:20

Generated On: 09 Jun 2021 17:35:47

[Participant ID](#)

US3412262

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

US3412262

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" 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) 13 Feb 2021 05:05:07

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Date of Informed Consent (*dd MMM yyyy*) 17 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 05:05:07

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Condition	OSTEOARTHRITIS LEFT HIP PAIN
Start date (dd MMM yyyy)	UN FEB 2020
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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Condition	CATARACTS.
Start date (dd MMM yyyy)	UN JAN 2020
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 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:05:07

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:14 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:14
Height (<i>xxx.x</i>)	182.7 cm
Weight (<i>xxx.x</i>)	84.4 kg
BMI (<i>xxx.x</i>)	25.28514 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:05:07

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes
No

Specify

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:05:07

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EXPOSURE TO SOCIAL
INTERACTIONS GOES TO
GROCERY STORE, RUNS
ERRANDS, DOCTORS
APPOINTMENT, SEEING
FAMILY MEMBERS, WATCH
NEIGHBORS DOGS, INCREASE
RISK OF COVID 19
COMPLICATIONS DUE TO AGE
OVER 65

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 17 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186725

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) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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 (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:44 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:44
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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 (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:44 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 16:44
Temperature (<i>xxx.x</i>)	95.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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) 13 Feb 2021 05:05:08

Generated On: 09 Jun 2021 17:35:47

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 16:05

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) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 17 AUG 2020

Collection time (*00:00-23:59*) 15:40 (24 HR)

Collection date and time (derived) 17 AUG 2020 15:40

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:05:08

Generated On: 09 Jun 2021 17:35:47

Collection date (<i>dd MMM yyyy</i>)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	17 AUG 2020 15:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:08

Generated On: 09 Jun 2021 17:35:47

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: 09 Jun 2021 17:35:47

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 95.7 °F

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

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

PC Time Stamp 17 AUG 2020 16:51

PC Open Date & Time 17 AUG 2020 16:25

PC Close Date & Time 17 AUG 2020 18:55

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

PC Time Stamp	17 AUG 2020 21:22
PC Open Date & Time	17 AUG 2020 19:50
PC Close Date & Time	18 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

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	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 21:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 AUG 2020 02:53
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

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** 97.5 °F

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

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

PC Time Stamp 20 AUG 2020 20:53

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 AUG 2020 21:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 AUG 2020 20:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.5 °F

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

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

PC Time Stamp 23 AUG 2020 21:01
PC Open Date & Time 23 AUG 2020 12:00
PC Close Date & Time 24 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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	17 AUG 2020 16:54
PC Open Date & Time	17 AUG 2020 16:25
PC Close Date & Time	17 AUG 2020 18:55

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

17 AUG 2020 19:50

PC Close Date & Time

18 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 3

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

20 AUG 2020 02:55

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

20 AUG 2020 20:54

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 5

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	21 AUG 2020 21:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 AUG 2020 20:56

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 7

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

23 AUG 2020 21:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

No
Yes

PC Time stamp	17 AUG 2020 16:56
PC Open Date & Time	17 AUG 2020 16:25
PC Close Date & Time	17 AUG 2020 18:55

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

No

Yes

PC Time stamp

PC Open Date & Time

17 AUG 2020 19:50

PC Close Date & Time

18 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

Yes

PC Time stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 02:55
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 20:55
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 21:09
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 20:57
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 21:02
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3412262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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 (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:00
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:11
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 11:40

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

US3412262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:15 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:15

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Collection date (<i>dd MMM yyyy</i>)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	14 SEP 2020 11:24
Nasopharyngeal Swab 2	No		

US3412262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 97.5 °F

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

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

PC Time Stamp	14 SEP 2020 12:27
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 14:30

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp 14 SEP 2020 21:03
PC Open Date & Time 14 SEP 2020 15:25
PC Close Date & Time 15 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

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	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 21:03
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 21:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 21:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 SEP 2020 21:02
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 21:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 21:03
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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	14 SEP 2020 12:28
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 14:30

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

14 SEP 2020 21:04

PC Open Date & Time

14 SEP 2020 15:25

PC Close Date & Time

15 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 2

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	15 SEP 2020 21:04
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 3

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

16 SEP 2020 21:02

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 4

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

17 SEP 2020 21:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 5

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

18 SEP 2020 21:02

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 6

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

19 SEP 2020 21:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 7

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

20 SEP 2020 21:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

No

Yes

PC Time stamp	14 SEP 2020 12:29
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 14:30

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

No

Yes

PC Time stamp	14 SEP 2020 21:05
PC Open Date & Time	14 SEP 2020 15:25
PC Close Date & Time	15 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 21:04
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 21:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 21:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 21:03
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 21:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 21:04
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3412262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:07

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 OCT 2020

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

Folder OID VISIT3

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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) _____

US3412262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

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.

US3412262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 19 OCT 2020

Collection time (*00:00-23:59*) 10:40 (24 HR)

Collection date and time (derived) 19 OCT 2020 10:40

US3412262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:05:22

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 19 OCT 2020 19:58:18

Patient Cloud Open Date & Time 17 OCT 2020 00:01

Patient Cloud Close Date & Time 21 OCT 2020 23:59

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 26 OCT 2020 19:48:54

Patient Cloud Open Date & Time 24 OCT 2020 00:01

Patient Cloud Close Date & Time 28 OCT 2020 23:59

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 02 NOV 2020 19:46:47

Patient Cloud Open Date & Time 31 OCT 2020 00:01

Patient Cloud Close Date & Time 04 NOV 2020 23:59

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 16 NOV 2020 19:42:51

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 <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	25 NOV 2020 12:08:43
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	02 DEC 2020 07:54:58
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	09 DEC 2020 17:57:37
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	16 DEC 2020 02:48:04
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 23 DEC 2020 20:06:37

Patient Cloud Open Date & Time 23 DEC 2020 00:01

Patient Cloud Close Date & Time 27 DEC 2020 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 <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	30 DEC 2020 20:41:52
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

06 JAN 2021 12:13:30

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 13 JAN 2021 22:34:05

Patient Cloud Open Date & Time 13 JAN 2021 00:01

Patient Cloud Close Date & Time 17 JAN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 10:43:44
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 28 JAN 2021 12:58:39

Patient Cloud Open Date & Time 27 JAN 2021 00:01

Patient Cloud Close Date & Time 31 JAN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 03 FEB 2021 09:19:43

Patient Cloud Open Date & Time 03 FEB 2021 00:01

Patient Cloud Close Date & Time 07 FEB 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	10 FEB 2021 09:56:24
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	18 FEB 2021 12:36:24
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 12:40:15
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 04 MAR 2021 08:47:07

Patient Cloud Open Date & Time 03 MAR 2021 00:01

Patient Cloud Close Date & Time 07 MAR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 10 MAR 2021 09:03:02

Patient Cloud Open Date & Time 10 MAR 2021 00:01

Patient Cloud Close Date & Time 14 MAR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 11:35:15
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 09:05:30
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 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	31 MAR 2021 13:27:57
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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	07 APR 2021 13:44:13
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 12:55:21
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 250

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

No

Yes

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

No

Yes

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

Date and time of submission 21 APR 2021 06:05:44

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 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	28 APR 2021 09:02:36
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 09 MAY 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 292

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 08 AUG 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 390

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 397

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 26 SEP 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 17 OCT 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 31 OCT 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 05 DEC 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 12 DEC 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 495

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 544

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 13 FEB 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 551

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 642

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 649

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

Date and time of submission

Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 684

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 705

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 14 AUG 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 754

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

[Patient Cloud Close Date & Time](#) 09 OCT 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:35:47

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		04 MAR 2021 08:47:32

US3412262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:39:06

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:39:06

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:21

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3412262

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID VISIT4

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

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) _____

US3412262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

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.

US3412262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 09:56 (24 HR)

Collection date and time (derived) 22 MAR 2021 09:56

US3412262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 APR 2021

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

Comments LEFT VM ON 12 APR 2021.
PATIENT CALLED BACK SAME
If Contact Not Made, please provide Comments DAY.

US3412262

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:52

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412262

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

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 _____

US3412262

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3412262

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:35:47

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"/>

US3412262

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:35:47

Generate Next COVID-19 Assessment

Yes

No

US3412262

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:57:21

Generated On: 09 Jun 2021 17:35:47

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 JAN 2021

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

Folder OID UNBLND_DECIDE

US3412262

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:57:20

Generated On: 09 Jun 2021 17:35:47

Date of updated informed consent (*dd MMM yyyy*) 15 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*) 15 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 _____

US3412262

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:57:20

Generated On: 09 Jun 2021 17:35:47

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 JAN 2021

Collection time (*00:00-23:59*) 13:22 (24 HR)

Collection date and time (derived) 15 JAN 2021 13:22

US3412262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:57:20

Generated On: 09 Jun 2021 17:35:47

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 JAN 2021

Collection time (*00:00 - 23:59*) 13:24

Collection Date and Time (derived) 15 JAN 2021 13:24

US3412262

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

AEID USA-US061-2021-MRNA-1273-P30
1000020

Adverse event WORSENING L HIP OA

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 1 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 21 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 21 APR 2021

Hospital Discharge Date (dd MMM yyyy) 24 APR 2021

Admitted to ICU? Yes
No
Unknown

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

SUBJECT NOTIFIED OUT SITE
AT 1200 ON 28 APR 2021 OF
WORSENING L HIP OA.
SUBJECT'S L HIP OA
WORSENERD 01 APR 2021 AND
ON 21 APR 2021 SUBJECT WAS
ADMITTED FOR L HIP
REPLACEMENT SURGERY AT IU
HEALTH SAXONY. SUBJECT
WAS DISCHARGED ON 24 APR
2021 AND WAS SENT TO REHAB
AT ALLISONVILLE MEADOWS
IN FISHERS, INDIANA. SUBJECT
IS CURRENTLY STILL IN
REHAB.

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

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:42:12

Generated On: 09 Jun 2021 17:35:47

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

Yes

No

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

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:24:05

Generated On: 09 Jun 2021 17:35:47

Name of Medication MELOXICAM

Prophylaxis Yes
No

Indication HIP PAIN

Dose per administration 15

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 1622

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:24:05

Generated On: 09 Jun 2021 17:35:47

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 FEB 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:42:12

Generated On: 09 Jun 2021 17:35:47

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3412262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:35:47

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

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

SAEID	USA-US061-2021-MRNA-1273-P301000020
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 23:57:20

Generated On: 09 Jun 2021 17:35:47

SAEID	USA-US061-2021-MRNA-1273-P301000020
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	28/APR/2021 14:00
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.	<input checked="" type="checkbox"/> True

Audit

US3412262 (Prod: New Horizons Clinical Research)

US3412262

Form: Participant Creation

Generated On: 09 Jun 2021 17:35:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:40:24
User entered 'US3412262'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:40:16

US3412262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:13
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:22

US3412262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:13
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:40:17

US3412262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:13
User entered 'Clinic (Clinic)'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:22

US3412262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'SCRN'	System	17 Aug 2020 20:28:22

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:40:18

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '69'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'YEARS'	System	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '69'	System	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered 'Male (M)'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '1'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered empty.	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:47

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:28
User entered '0'	Zachary Eardley (b) (4)	17 Aug 2020 20:28:43

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered '17 Aug 2020'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'Aug 2020'	System	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '2020'	System	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered 'Amendment 2 (2)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered empty.	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered empty.	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered 'No (N)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:09

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:40:17

US3412262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '1'	System	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:10
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:35:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:14
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:04:57

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:55:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:55:42
Data point term sent to Coder	System	24 Aug 2020 16:07:57
User entered 'Osteoarthritis left hip pain'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered 'UN Feb 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'Feb 2020'	System	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '2020'	System	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	24 Aug 2020 16:07:27

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 15:31:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 15:31:57
Data point term sent to Coder	System	25 Sep 2020 12:32:04
User entered 'cataracts.'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered 'un Jan 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered '0'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered 'un Jan 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:13:46
User entered '0'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'Jan 2020'	System	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '2020'	System	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'Jan 2020'	System	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '2020'	System	25 Sep 2020 12:31:10

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered '14:14'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '17 Aug 2020 14:14'	System	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered '182.7' cm	Mylene Asmar-Rios	24 Aug 2020 16:08:41
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered '84.4' kg	Mylene Asmar-Rios	24 Aug 2020 16:08:41
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
Amendment Manager: User entered '25.28514'	System	17 Sep 2020 00:00:34
User entered '25.3'	System	24 Aug 2020 16:08:41
DataPoint set to visible.	System	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'kg/m2'	System	24 Aug 2020 16:08:41
DataPoint set to visible.	System	17 Aug 2020 20:29:14

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 12:31:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 12:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:08:41
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 12:31:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 12:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:08:41
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'bpm'	System	25 Sep 2020 12:31:37
User entered empty.	System	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 12:31:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 12:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:08:41
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'breaths/min'	System	25 Sep 2020 12:31:37
User entered empty.	System	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 12:31:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 12:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:08:41
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'mmHg'	System	25 Sep 2020 12:31:37
User entered empty.	System	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 12:31:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 12:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:08:41
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'mmHg'	System	25 Sep 2020 12:31:37
User entered empty.	System	24 Aug 2020 16:08:41

US3412262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:13
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:09:01

US3412262

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:15:13
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		24 Sep 2020 10:27:07
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 15:51:11
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:09:01

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered 'EXPOSURE TO SOCIAL INTERACTIONS GOES TO GROCERY STORE, RUNS ERRANDS, DOCTORS APPOINTMENT, SEEING FAMILY MEMBERS, WATCH NEIGHBORS DOGS, INCREASE RISK OF COVID 19 COMPLICATIONS DUE TO AGE OVER 65'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:20:22
DataPoint Un-verified.		07 Oct 2020 20:19:53
DataPoint Verified.		07 Oct 2020 20:19:50
User entered '1'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:19:50
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:14:52

US3412262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:09
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:28

US3412262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:09
User entered '17 Aug 2020'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:28

US3412262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:09
User entered 'Clinic (Clinic)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:28

US3412262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'VISIT1'	System	17 Aug 2020 20:29:28

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:20

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:06:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:06:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:49:20
User entered '186725' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:20

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:20

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).		30 Sep 2020 05:13:54
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:40
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:26
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 13:09:01

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:26

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:26

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:26

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:34:26

US3412262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:21:19
User entered 'No (N)'	Jacob sekinger (b) (4)	25 Sep 2020 12:34:26
Amendment Manager: DataPoint set to visible.	(b) (4)	System
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 10:23:06 19 Sep 2020 07:42:31

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '14:44'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '17 Aug 2020 14:44'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '36.1' C	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '56'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'bpm'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '14'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'breaths/min'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '122'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '78'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '16:44'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '17 Aug 2020 16:44'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:39:53
User closed query 'Please comment whether temperature is CS or NCS' (Site from CRA).	(b) (4)	04 Nov 2020 14:39:51
User closed query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4)	20 Oct 2020 13:32:14
Query 'Please comment whether temperature is CS or NCS' answered with 'NCS' (Site from CRA).	Mylene Asmar-Rios (b) (4)	09 Oct 2020 15:16:33
Query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' answered with 'NOT CLINICALLY SIGNIFICANT' (Site from DM).	Mylene Asmar-Rios (b) (4)	09 Oct 2020 15:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 20:23:18
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:23:12
User opened query 'Please comment whether temperature is CS or NCS' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 20:23:02
User opened query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:07:28
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 13:06:42
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per protocol, within normal range.' (Site from System).	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:35:03
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:00:34

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '95.7' F	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '62'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'bpm'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '18'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'breaths/min'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '128'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:12
User entered '76'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	24 Aug 2020 16:22:49

US3412262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:22
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:23:39

US3412262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:22
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:23:39

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered empty.	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered empty.	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered '17 Aug 2020'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered '16:05'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '17 Aug 2020 16:05'	System	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:41
User entered 'Left Arm (LEFT ARM)'	Zachary Eardley (b) (4)	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
DataPoint Verified.		07 Oct 2020 20:23:41
User entered 'ONCE'	System	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:29:56

US3412262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:57
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:36:09

US3412262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:57
User entered '17 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:36:09

US3412262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:23:57
User entered '15:40'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:36:09

US3412262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '17 Aug 2020 15:40'	System	25 Sep 2020 12:36:09

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:04
User entered '17 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:04
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:04
User entered '15:35'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '17 Aug 2020 15:35'	System	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:04
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:04
User entered empty.	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered empty.	System	25 Sep 2020 12:37:30

US3412262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:24:09
User entered 'Yes (Y)'		31 Aug 2020 18:36:01

US3412262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	31 Aug 2020 18:36:01

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:51:15', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f7434847-c058-4517-92c1-78aa6abc2523' User entered 'Yes (Y)'	System	17 Aug 2020 20:51:58
	System	17 Aug 2020 20:51:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:51:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f7434847-c058-4517-92c1-78aa6abc2523' User entered '95.7'	System	17 Aug 2020 20:51:58
	System	17 Aug 2020 20:51:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:51:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f7434847-c058-4517-92c1-78aa6abc2523' User entered 'No (N)'	System	17 Aug 2020 20:51:58
	System	17 Aug 2020 20:51:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:51:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f7434847-c058-4517-92c1-78aa6abc2523' User entered '17 Aug 2020 16:51'	System	17 Aug 2020 20:51:58
	System	17 Aug 2020 20:51:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 18:55'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T21:21:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3e822027-2b23-4727-aec0-3a6cc403cd98'	System	18 Aug 2020 01:22:21
User entered 'Yes (Y)'	System	18 Aug 2020 01:22:21

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T21:22:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3e822027-2b23-4727-aec0-3a6cc403cd98'	System	18 Aug 2020 01:22:21
User entered '96.5'	System	18 Aug 2020 01:22:21

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T21:22:05', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3e822027-2b23-4727-aec0-3a6cc403cd98'	System	18 Aug 2020 01:22:21
User entered 'No (N)'	System	18 Aug 2020 01:22:21

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T21:22:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3e822027-2b23-4727-aec0-3a6cc403cd98' User entered '17 Aug 2020 21:22'	System	18 Aug 2020 01:22:21
	System	18 Aug 2020 01:22:21

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 19:50'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 2'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-18T21:17:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '29de080c-5453-4891-99a9-2957d1eaac9c' User entered 'Yes (Y)'	System	19 Aug 2020 01:17:30
	System	19 Aug 2020 01:17:30

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-18T21:17:13', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '29de080c-5453-4891-99a9-2957d1eaac9c' User entered '97.9'	System	19 Aug 2020 01:17:30
	System	19 Aug 2020 01:17:30

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-18T21:17:17', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '29de080c-5453-4891-99a9-2957d1eaac9c'	System	19 Aug 2020 01:17:30
User entered 'No (N)'	System	19 Aug 2020 01:17:30

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-18T21:17:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '29de080c-5453-4891-99a9-2957d1eaac9c' User entered '18 Aug 2020 21:17'	System	19 Aug 2020 01:17:30
	System	19 Aug 2020 01:17:30

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 3'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:53:30', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a931bd5e-6b07-42b7-99f9-97d831fd632f' User entered 'Yes (Y)'	System	20 Aug 2020 06:53:53
	System	20 Aug 2020 06:53:53

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:53:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a931bd5e-6b07-42b7-99f9-97d831fd632f' User entered '96.6'	System	20 Aug 2020 06:53:53
	System	20 Aug 2020 06:53:53

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:53:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a931bd5e-6b07-42b7-99f9-97d831fd632f' User entered 'No (N)'	System	20 Aug 2020 06:53:53
	System	20 Aug 2020 06:53:53

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:53:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a931bd5e-6b07-42b7-99f9-97d831fd632f' User entered '20 Aug 2020 02:53'	System	20 Aug 2020 06:53:53
	System	20 Aug 2020 06:53:53

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 4'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:53:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'def6d7d9-ecc8-4fa1-b22c-8b0a60c21284' User entered 'Yes (Y)'	System	21 Aug 2020 00:53:44
	System	21 Aug 2020 00:53:44

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:53:29', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'def6d7d9-ecc8-4fa1-b22c-8b0a60c21284' User entered '97.5'	System	21 Aug 2020 00:53:44
	System	21 Aug 2020 00:53:44

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:53:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'def6d7d9-ecc8-4fa1-b22c-8b0a60c21284'	System	21 Aug 2020 00:53:44
User entered 'No (N)'	System	21 Aug 2020 00:53:44

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:53:42', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'def6d7d9-ecc8-4fa1-b22c-8b0a60c21284' User entered '20 Aug 2020 20:53'	System	21 Aug 2020 00:53:44
	System	21 Aug 2020 00:53:44

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 5'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '62674660-44a4-46d2-a7a6-aef079d14406' User entered 'Yes (Y)'	System	22 Aug 2020 01:08:58
	System	22 Aug 2020 01:08:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:42', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '62674660-44a4-46d2-a7a6-aef079d14406' User entered '97.2'	System	22 Aug 2020 01:08:58
	System	22 Aug 2020 01:08:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '62674660-44a4-46d2-a7a6-aef079d14406'	System	22 Aug 2020 01:08:58
User entered 'No (N)'	System	22 Aug 2020 01:08:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '62674660-44a4-46d2-a7a6-ae079d14406' User entered '21 Aug 2020 21:08'	System	22 Aug 2020 01:08:58
	System	22 Aug 2020 01:08:58

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 6'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:55:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '24c57057-f0da-46ca-bdd8-b39415dc2eab' User entered 'Yes (Y)'	System	25 Aug 2020 06:18:31
	System	25 Aug 2020 06:18:31

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:55:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '24c57057-f0da-46ca-bdd8-b39415dc2eab' User entered '97.2'	System	25 Aug 2020 06:18:31
	System	25 Aug 2020 06:18:31

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:55:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '24c57057-f0da-46ca-bdd8-b39415dc2eab' User entered 'No (N)'	System	25 Aug 2020 06:18:31
	System	25 Aug 2020 06:18:31

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:55:58', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '24c57057-f0da-46ca-bdd8-b39415dc2eab' User entered '22 Aug 2020 20:55'	System	25 Aug 2020 06:18:31
	System	25 Aug 2020 06:18:31

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 7'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:29', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e0c80dba-776b-4a1e-a17f-cbe90afddb39' User entered 'Yes (Y)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:35', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e0c80dba-776b-4a1e-a17f-cbe90afddb39' User entered '97.5'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e0c80dba-776b-4a1e-a17f-cbe90afddb39'	System	25 Aug 2020 06:18:35
User entered 'No (N)'	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e0c80dba-776b-4a1e-a17f-cbe90afddb39' User entered '23 Aug 2020 21:01'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:54:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7a039bc4-4abc-421f-a322-acaac84ce1fe' User entered 'None (1)'	System	17 Aug 2020 20:54:56
	System	17 Aug 2020 20:54:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:54:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7a039bc4-4abc-421f-a322-acaac84ce1fe' User entered 'No (N)'	System	17 Aug 2020 20:54:56
	System	17 Aug 2020 20:54:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:54:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7a039bc4-4abc-421f-a322-acaac84ce1fe' User entered 'No (N)'	System	17 Aug 2020 20:54:56
	System	17 Aug 2020 20:54:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:54:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7a039bc4-4abc-421f-a322-acaac84ce1fe'	System	17 Aug 2020 20:54:56
User entered 'None (1)'	System	17 Aug 2020 20:54:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:54:54', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7a039bc4-4abc-421f-a322-acaac84ce1fe' User entered '17 Aug 2020 16:54'	System	17 Aug 2020 20:54:56
	System	17 Aug 2020 20:54:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 18:55'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 19:50'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 2'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 3'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:54:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1ae2c5d7-0112-4bc1-8254-5c1b0e2d49e8' User entered 'None (1)'	System	20 Aug 2020 06:55:04
	System	20 Aug 2020 06:55:04

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:54:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1ae2c5d7-0112-4bc1-8254-5c1b0e2d49e8' User entered 'No (N)'	System	20 Aug 2020 06:55:04
	System	20 Aug 2020 06:55:04

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:54:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1ae2c5d7-0112-4bc1-8254-5c1b0e2d49e8' User entered 'No (N)'	System	20 Aug 2020 06:55:04
	System	20 Aug 2020 06:55:04

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:54:53', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1ae2c5d7-0112-4bc1-8254-5c1b0e2d49e8' User entered 'None (1)'	System	20 Aug 2020 06:55:04
	System	20 Aug 2020 06:55:04

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1ae2c5d7-0112-4bc1-8254-5c1b0e2d49e8' User entered '20 Aug 2020 02:55'	System	20 Aug 2020 06:55:04
	System	20 Aug 2020 06:55:04

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 4'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:53:52', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ba2c2355-c8a9-4093-9e26-84fe103e5fc0'	System	21 Aug 2020 00:54:29
User entered 'None (1)'	System	21 Aug 2020 00:54:29

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ba2c2355-c8a9-4093-9e26-84fe103e5fc0'	System	21 Aug 2020 00:54:29
User entered 'No (N)'	System	21 Aug 2020 00:54:29

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ba2c2355-c8a9-4093-9e26-84fe103e5fc0'	System	21 Aug 2020 00:54:29
User entered 'No (N)'	System	21 Aug 2020 00:54:29

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:17', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ba2c2355-c8a9-4093-9e26-84fe103e5fc0'	System	21 Aug 2020 00:54:29
User entered 'None (1)'	System	21 Aug 2020 00:54:29

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:27', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ba2c2355-c8a9-4093-9e26-84fe103e5fc0' User entered '20 Aug 2020 20:54'	System	21 Aug 2020 00:54:29
	System	21 Aug 2020 00:54:29

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 5'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:07:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd7c2236d-5f86-4687-acfb-46c7b461fd7c'	System	22 Aug 2020 01:08:20
User entered 'None (1)'	System	22 Aug 2020 01:08:20

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:07:45', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd7c2236d-5f86-4687-acfb-46c7b461fd7c' User entered 'No (N)'	System	22 Aug 2020 01:08:20
	System	22 Aug 2020 01:08:20

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:07:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd7c2236d-5f86-4687-acfb-46c7b461fd7c' User entered 'No (N)'	System	22 Aug 2020 01:08:20
	System	22 Aug 2020 01:08:20

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:06', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd7c2236d-5f86-4687-acfb-46c7b461fd7c'	System	22 Aug 2020 01:08:20
User entered 'None (1)'	System	22 Aug 2020 01:08:20

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:08:19', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd7c2236d-5f86-4687-acfb-46c7b461fd7c' User entered '21 Aug 2020 21:08'	System	22 Aug 2020 01:08:20
	System	22 Aug 2020 01:08:20

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 6'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:10', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e6041d4d-93fe-4146-8535-71e5c50e7bf9'	System	25 Aug 2020 06:18:32
User entered 'None (1)'	System	25 Aug 2020 06:18:32

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:14', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e6041d4d-93fe-4146-8535-71e5c50e7bf9'	System	25 Aug 2020 06:18:32
User entered 'No (N)'	System	25 Aug 2020 06:18:32

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:20', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e6041d4d-93fe-4146-8535-71e5c50e7bf9'	System	25 Aug 2020 06:18:32
User entered 'No (N)'	System	25 Aug 2020 06:18:32

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e6041d4d-93fe-4146-8535-71e5c50e7bf9'	System	25 Aug 2020 06:18:32
User entered 'None (1)'	System	25 Aug 2020 06:18:32

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:40', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e6041d4d-93fe-4146-8535-71e5c50e7bf9' User entered '22 Aug 2020 20:56'	System	25 Aug 2020 06:18:32
	System	25 Aug 2020 06:18:32

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 7'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:53', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1fdccf36-393b-4fd5-a674-3c24b4d6f5fa'	System	25 Aug 2020 06:18:34
User entered 'None (1)'	System	25 Aug 2020 06:18:34

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:01:57', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1fdccf36-393b-4fd5-a674-3c24b4d6f5fa'	System	25 Aug 2020 06:18:34
User entered 'No (N)'	System	25 Aug 2020 06:18:34

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:01', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1fdccf36-393b-4fd5-a674-3c24b4d6f5fa'	System	25 Aug 2020 06:18:34
User entered 'No (N)'	System	25 Aug 2020 06:18:34

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:10', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1fdccf36-393b-4fd5-a674-3c24b4d6f5fa'	System	25 Aug 2020 06:18:34
User entered 'None (1)'	System	25 Aug 2020 06:18:34

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:18', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1fdccf36-393b-4fd5-a674-3c24b4d6f5fa' User entered '23 Aug 2020 21:02'	System	25 Aug 2020 06:18:34
	System	25 Aug 2020 06:18:34

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:56:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:19', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:24', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:36', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'None (0)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:55:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered 'No (N)'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-17T16:56:17', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3ccb8128-6436-4721-b006-e222a08191f4' User entered '17 Aug 2020 16:56'	System	17 Aug 2020 20:56:21
	System	17 Aug 2020 20:56:21

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 18:55'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Aug 2020 19:50'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 2'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 3'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:14', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:18', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:25', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'None (0)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:36', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered 'No (N)'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T02:55:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '894a90c7-a5f1-4c17-981b-e3fae2ae32dc' User entered '20 Aug 2020 02:55'	System	20 Aug 2020 06:55:58
	System	20 Aug 2020 06:55:58

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 4'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:54:53', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered 'None (0)'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:55:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b'	System	21 Aug 2020 00:55:14
User entered 'No (N)'	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-20T20:55:12', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c2313927-3e7f-4877-835a-c9d388316f2b' User entered '20 Aug 2020 20:55'	System	21 Aug 2020 00:55:14
	System	21 Aug 2020 00:55:14

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 5'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:04', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:15', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:18', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered 'None (0)'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac'	System	22 Aug 2020 01:09:49
User entered 'No (N)'	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-21T21:09:48', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '92727166-f7e5-4e3d-adee-20dcc6fb04ac' User entered '21 Aug 2020 21:09'	System	22 Aug 2020 01:09:49
	System	22 Aug 2020 01:09:49

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 6'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:53', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:56:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:57:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:57:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'None (0)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:57:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered 'No (N)'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-22T20:57:15', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '82463b70-ed8f-4f89-927b-492d83c41ceb' User entered '22 Aug 2020 20:57'	System	25 Aug 2020 06:18:33
	System	25 Aug 2020 06:18:33

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 7'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:23', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:30', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:36', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'None (0)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered 'No (N)'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-08-23T21:02:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1aea02f3-9e36-479e-b3c3-089d8260d756' User entered '23 Aug 2020 21:02'	System	25 Aug 2020 06:18:35
	System	25 Aug 2020 06:18:35

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:29:56

US3412262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:26:46
User entered 'Yes (Y)'		31 Aug 2020 18:36:37

US3412262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:26:46
User entered '24 Aug 2020'		31 Aug 2020 18:36:37

US3412262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:26:46
User entered 'Contact Made (CONTACT MADE)'		31 Aug 2020 18:36:37

US3412262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:26:46
User entered empty.		31 Aug 2020 18:36:37

US3412262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:27:54
User entered 'Yes (Y)'		31 Aug 2020 18:36:43

US3412262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'I'	System	31 Aug 2020 18:36:43

US3412262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:28:22
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	31 Aug 2020 18:37:11
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	31 Aug 2020 18:36:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 18:36:57

US3412262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:28:22
User entered '31 Aug 2020'		31 Aug 2020 18:36:57

US3412262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:28:22
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error		31 Aug 2020 18:37:11
User entered empty.		31 Aug 2020 18:36:57

US3412262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:28:22
User entered empty.		31 Aug 2020 18:36:57

US3412262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:28:26
User entered 'Yes (Y)'		31 Aug 2020 18:37:16

US3412262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'I'	System	31 Aug 2020 18:37:16

US3412262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:29:53
User entered 'Yes (Y)'		08 Sep 2020 17:57:18

US3412262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:29:53
User entered '08 Sep 2020'		08 Sep 2020 17:57:18

US3412262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:29:53
User entered 'Contact Made (CONTACT MADE)'		08 Sep 2020 17:57:18

US3412262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:29:53
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:57:18

US3412262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:29:55
User entered 'Yes (Y)'		08 Sep 2020 17:57:22

US3412262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	08 Sep 2020 17:57:22

US3412262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:06:20
User entered 'Yes (Y)'		14 Sep 2020 15:51:11

US3412262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:06:20
User entered '14 Sep 2020'		14 Sep 2020 15:51:11

US3412262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:06:20
User entered 'Clinic (Clinic)'		14 Sep 2020 15:51:11

US3412262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'VISIT2'	System	14 Sep 2020 15:51:11

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '14 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '11:00'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '14 Sep 2020 11:00'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '36.7' C	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered empty.	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '68'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'bpm'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '14'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'breaths/min'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '126'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '82'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '14 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '12:11'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '14 Sep 2020 12:11'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '97.5' F	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered empty.	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '66'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'bpm'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '16'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'breaths/min'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '122'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:31
User entered '80'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'mmHg'	System	25 Sep 2020 12:44:36

US3412262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:41
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:51

US3412262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:08:41
User entered '14 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:44:51

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered 'Yes (Y)'		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered empty.		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered empty.		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered '14 Sep 2020'		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered '11:40'		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '14 Sep 2020 11:40'	System	14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:01
User entered 'Left Arm (LEFT ARM)'		14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
DataPoint Verified.		08 Oct 2020 12:09:01
User entered 'ONCE'	System	14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 15:51:44

US3412262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:45:10

US3412262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:13
User entered '14 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:45:10

US3412262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:13
User entered '11:15'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:45:10

US3412262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '14 Sep 2020 11:15'	System	25 Sep 2020 12:45:10

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:21
User entered '14 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:21
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:21
User entered '11:24'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '14 Sep 2020 11:24'	System	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:21
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:21
User entered empty.	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered empty.	System	25 Sep 2020 12:46:05

US3412262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:09:25
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	21 Sep 2020 19:54:49

US3412262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	21 Sep 2020 19:54:49

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:27:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f87e67d5-0dd3-474e-8f29-bb732b76e118' User entered 'Yes (Y)'	System	14 Sep 2020 16:27:48
	System	14 Sep 2020 16:27:48

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:27:21', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f87e67d5-0dd3-474e-8f29-bb732b76e118' User entered '97.5'	System	14 Sep 2020 16:27:48
	System	14 Sep 2020 16:27:48

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:27:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f87e67d5-0dd3-474e-8f29-bb732b76e118' User entered 'No (N)'	System	14 Sep 2020 16:27:48
	System	14 Sep 2020 16:27:48

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:27:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f87e67d5-0dd3-474e-8f29-bb732b76e118' User entered '14 Sep 2020 12:27'	System	14 Sep 2020 16:27:48
	System	14 Sep 2020 16:27:48

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 14:30'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:03:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0d514dd5-aa06-46fb-ab63-900be53c43c2' User entered 'Yes (Y)'	System	15 Sep 2020 01:03:53
	System	15 Sep 2020 01:03:53

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:03:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0d514dd5-aa06-46fb-ab63-900be53c43c2' User entered '96.8'	System	15 Sep 2020 01:03:53
	System	15 Sep 2020 01:03:53

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:03:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0d514dd5-aa06-46fb-ab63-900be53c43c2'	System	15 Sep 2020 01:03:53
User entered 'No (N)'	System	15 Sep 2020 01:03:53

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:03:50', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0d514dd5-aa06-46fb-ab63-900be53c43c2' User entered '14 Sep 2020 21:03'	System	15 Sep 2020 01:03:53
	System	15 Sep 2020 01:03:53

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 15:25'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 2'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:02:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6af9655-4f86-47cd-b281-4fed98865a3d' User entered 'Yes (Y)'	System	16 Sep 2020 01:03:15
	System	16 Sep 2020 01:03:15

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:02:57', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6afc9655-4f86-47cd-b281-4fed98865a3d' User entered '97.9'	System	16 Sep 2020 01:03:15
	System	16 Sep 2020 01:03:15

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6afc9655-4f86-47cd-b281-4fed98865a3d'	System	16 Sep 2020 01:03:15
User entered 'No (N)'	System	16 Sep 2020 01:03:15

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:11', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6afc9655-4f86-47cd-b281-4fed98865a3d'	System	16 Sep 2020 01:03:15
User entered '15 Sep 2020 21:03'	System	16 Sep 2020 01:03:15

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 3'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:01:35', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '03bad348-43a4-4af3-9048-4a50d2830a14' User entered 'Yes (Y)'	System	17 Sep 2020 01:01:55
	System	17 Sep 2020 01:01:55

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:01:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '03bad348-43a4-4af3-9048-4a50d2830a14' User entered '96.5'	System	17 Sep 2020 01:01:55
	System	17 Sep 2020 01:01:55

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:01:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '03bad348-43a4-4af3-9048-4a50d2830a14' User entered 'No (N)'	System	17 Sep 2020 01:01:55
	System	17 Sep 2020 01:01:55

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:01:52', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '03bad348-43a4-4af3-9048-4a50d2830a14' User entered '16 Sep 2020 21:01'	System	17 Sep 2020 01:01:55
	System	17 Sep 2020 01:01:55

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 4'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:31', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1afaa68d-3e1f-450e-9af2-fc81e9842ef7' User entered 'Yes (Y)'	System	18 Sep 2020 01:01:50
	System	18 Sep 2020 01:01:50

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1afaa68d-3e1f-450e-9af2-fc81e9842ef7' User entered '96.1'	System	18 Sep 2020 01:01:50
	System	18 Sep 2020 01:01:50

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1afaa68d-3e1f-450e-9af2-fc81e9842ef7'	System	18 Sep 2020 01:01:50
User entered 'No (N)'	System	18 Sep 2020 01:01:50

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1afaa68d-3e1f-450e-9af2-fc81e9842ef7' User entered '17 Sep 2020 21:01'	System	18 Sep 2020 01:01:50
	System	18 Sep 2020 01:01:50

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 5'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:01:57', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a57d6d95-4bb1-490f-af3d-ccf86ddbea49' User entered 'Yes (Y)'	System	19 Sep 2020 01:02:21
	System	19 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a57d6d95-4bb1-490f-af3d-ccf86ddbea49' User entered '95.9'	System	19 Sep 2020 01:02:21
	System	19 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:12', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a57d6d95-4bb1-490f-af3d-ccf86ddbea49'	System	19 Sep 2020 01:02:21
User entered 'No (N)'	System	19 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a57d6d95-4bb1-490f-af3d-ccf86ddbea49' User entered '18 Sep 2020 21:02'	System	19 Sep 2020 01:02:21
	System	19 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 6'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:20', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a1bcbf39-146a-49aa-82fe-bb5fd8f1b9f8'	System	20 Sep 2020 01:01:39
User entered 'Yes (Y)'	System	20 Sep 2020 01:01:39

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a1bcbf39-146a-49aa-82fe-bb5fd8f1b9f8'	System	20 Sep 2020 01:01:39
User entered '97.0'	System	20 Sep 2020 01:01:39

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a1bcbf39-146a-49aa-82fe-bb5fd8f1b9f8'	System	20 Sep 2020 01:01:39
User entered 'No (N)'	System	20 Sep 2020 01:01:39

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a1bcbf39-146a-49aa-82fe-bb5fd8f1b9f8'	System	20 Sep 2020 01:01:39
User entered '19 Sep 2020 21:01'	System	20 Sep 2020 01:01:39

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 7'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:02:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd2d5213d-79e8-4bc4-86f5-b7ff5b90c764' User entered 'Yes (Y)'	System	21 Sep 2020 01:03:18
	System	21 Sep 2020 01:03:18

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd2d5213d-79e8-4bc4-86f5-b7ff5b90c764' User entered '96.5'	System	21 Sep 2020 01:03:18
	System	21 Sep 2020 01:03:18

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:09', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd2d5213d-79e8-4bc4-86f5-b7ff5b90c764'	System	21 Sep 2020 01:03:18
User entered 'No (N)'	System	21 Sep 2020 01:03:18

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'd2d5213d-79e8-4bc4-86f5-b7ff5b90c764'	System	21 Sep 2020 01:03:18
User entered '20 Sep 2020 21:03'	System	21 Sep 2020 01:03:18

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:27:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0128287e-42cf-4ae1-929e-d82c75c094b7'	System	14 Sep 2020 16:28:39
User entered 'None (1)'	System	14 Sep 2020 16:28:39

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0128287e-42cf-4ae1-929e-d82c75c094b7'	System	14 Sep 2020 16:28:39
User entered 'No (N)'	System	14 Sep 2020 16:28:39

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:09', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0128287e-42cf-4ae1-929e-d82c75c094b7'	System	14 Sep 2020 16:28:39
User entered 'No (N)'	System	14 Sep 2020 16:28:39

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0128287e-42cf-4ae1-929e-d82c75c094b7'	System	14 Sep 2020 16:28:39
User entered 'None (1)'	System	14 Sep 2020 16:28:39

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0128287e-42cf-4ae1-929e-d82c75c094b7'	System	14 Sep 2020 16:28:39
User entered '14 Sep 2020 12:28'	System	14 Sep 2020 16:28:39

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 14:30'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:03:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c8dbb7ce-7324-4375-9e3f-6bcb0df358d7'	System	15 Sep 2020 01:04:29
User entered 'None (1)'	System	15 Sep 2020 01:04:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:04', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c8dbb7ce-7324-4375-9e3f-6bcb0df358d7'	System	15 Sep 2020 01:04:29
User entered 'No (N)'	System	15 Sep 2020 01:04:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c8dbb7ce-7324-4375-9e3f-6bcb0df358d7'	System	15 Sep 2020 01:04:29
User entered 'No (N)'	System	15 Sep 2020 01:04:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:13', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c8dbb7ce-7324-4375-9e3f-6bcb0df358d7'	System	15 Sep 2020 01:04:29
User entered 'None (1)'	System	15 Sep 2020 01:04:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:25', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'c8dbb7ce-7324-4375-9e3f-6bcb0df358d7'	System	15 Sep 2020 01:04:29
User entered '14 Sep 2020 21:04'	System	15 Sep 2020 01:04:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 15:25'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 2'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1756f598-c47a-4d4f-955c-a30fb89bdfb2'	System	16 Sep 2020 01:04:12
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:04:12

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1756f598-c47a-4d4f-955c-a30fb89bdfb2'	System	16 Sep 2020 01:04:12
User entered 'No (N)'	System	16 Sep 2020 01:04:12

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1756f598-c47a-4d4f-955c-a30fb89bdfb2'	System	16 Sep 2020 01:04:12
User entered 'No (N)'	System	16 Sep 2020 01:04:12

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:03:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1756f598-c47a-4d4f-955c-a30fb89bdfb2'	System	16 Sep 2020 01:04:12
User entered 'None (1)'	System	16 Sep 2020 01:04:12

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1756f598-c47a-4d4f-955c-a30fb89bdfb2'	System	16 Sep 2020 01:04:12
User entered '15 Sep 2020 21:04'	System	16 Sep 2020 01:04:12

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 3'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:01:58', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e375ba2-a67d-4f53-90b3-34f9289ea43e' User entered 'None (1)'	System	17 Sep 2020 01:02:41
	System	17 Sep 2020 01:02:41

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e375ba2-a67d-4f53-90b3-34f9289ea43e' User entered 'No (N)'	System	17 Sep 2020 01:02:41
	System	17 Sep 2020 01:02:41

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:12', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e375ba2-a67d-4f53-90b3-34f9289ea43e' User entered 'No (N)'	System	17 Sep 2020 01:02:41
	System	17 Sep 2020 01:02:41

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:25', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e375ba2-a67d-4f53-90b3-34f9289ea43e' User entered 'None (1)'	System	17 Sep 2020 01:02:41
	System	17 Sep 2020 01:02:41

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:35', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e375ba2-a67d-4f53-90b3-34f9289ea43e' User entered '16 Sep 2020 21:02'	System	17 Sep 2020 01:02:41
	System	17 Sep 2020 01:02:41

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 4'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:53', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a3b1178d-90bf-44a5-a616-fbe0f14091ad'	System	18 Sep 2020 01:02:21
User entered 'None (1)'	System	18 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:01:58', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a3b1178d-90bf-44a5-a616-fbe0f14091ad'	System	18 Sep 2020 01:02:21
User entered 'No (N)'	System	18 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:01', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a3b1178d-90bf-44a5-a616-fbe0f14091ad'	System	18 Sep 2020 01:02:21
User entered 'No (N)'	System	18 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a3b1178d-90bf-44a5-a616-fbe0f14091ad'	System	18 Sep 2020 01:02:21
User entered 'None (1)'	System	18 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:17', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a3b1178d-90bf-44a5-a616-fbe0f14091ad' User entered '17 Sep 2020 21:02'	System	18 Sep 2020 01:02:21
	System	18 Sep 2020 01:02:21

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 5'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9299059c-63ee-4cfa-b529-8b2451863129'	System	19 Sep 2020 01:03:00
User entered 'None (1)'	System	19 Sep 2020 01:03:00

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9299059c-63ee-4cfa-b529-8b2451863129'	System	19 Sep 2020 01:03:00
User entered 'No (N)'	System	19 Sep 2020 01:03:00

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9299059c-63ee-4cfa-b529-8b2451863129' User entered 'No (N)'	System	19 Sep 2020 01:03:00
	System	19 Sep 2020 01:03:00

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9299059c-63ee-4cfa-b529-8b2451863129'	System	19 Sep 2020 01:03:00
User entered 'None (1)'	System	19 Sep 2020 01:03:00

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:02:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9299059c-63ee-4cfa-b529-8b2451863129' User entered '18 Sep 2020 21:02'	System	19 Sep 2020 01:03:00
	System	19 Sep 2020 01:03:00

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 6'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ca0c9ee5-7cc3-49fc-8afc-ad2d8c087652'	System	20 Sep 2020 01:02:29
User entered 'None (1)'	System	20 Sep 2020 01:02:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:01:54', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ca0c9ee5-7cc3-49fc-8afc-ad2d8c087652'	System	20 Sep 2020 01:02:29
User entered 'No (N)'	System	20 Sep 2020 01:02:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:01', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ca0c9ee5-7cc3-49fc-8afc-ad2d8c087652'	System	20 Sep 2020 01:02:29
User entered 'No (N)'	System	20 Sep 2020 01:02:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:09', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ca0c9ee5-7cc3-49fc-8afc-ad2d8c087652'	System	20 Sep 2020 01:02:29
User entered 'None (1)'	System	20 Sep 2020 01:02:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:27', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'ca0c9ee5-7cc3-49fc-8afc-ad2d8c087652' User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:29
	System	20 Sep 2020 01:02:29

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 7'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:25', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e93bcb82-5166-4baa-a7c4-7723a71ceca2'	System	21 Sep 2020 01:03:57
User entered 'None (1)'	System	21 Sep 2020 01:03:57

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e93bcb82-5166-4baa-a7c4-7723a71ceca2'	System	21 Sep 2020 01:03:57
User entered 'No (N)'	System	21 Sep 2020 01:03:57

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:40', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e93bcb82-5166-4baa-a7c4-7723a71ceca2'	System	21 Sep 2020 01:03:57
User entered 'No (N)'	System	21 Sep 2020 01:03:57

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e93bcb82-5166-4baa-a7c4-7723a71ceca2'	System	21 Sep 2020 01:03:57
User entered 'None (1)'	System	21 Sep 2020 01:03:57

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:03:55', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e93bcb82-5166-4baa-a7c4-7723a71ceca2' User entered '20 Sep 2020 21:03'	System	21 Sep 2020 01:03:57
	System	21 Sep 2020 01:03:57

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:45', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:49', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:52', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:28:59', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'None (0)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:29:04', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930' User entered 'No (N)'	System	14 Sep 2020 16:29:10
	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T12:29:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e59880ad-239e-44b2-aaaf-668b3cbbb930'	System	14 Sep 2020 16:29:10
User entered '14 Sep 2020 12:29'	System	14 Sep 2020 16:29:10

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 14:30'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:29', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'None (0)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'None (0)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'None (0)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:40', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503' User entered 'None (0)'	System	15 Sep 2020 01:05:09
	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'None (0)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'None (0)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:04:52', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered 'No (N)'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-14T21:05:03', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'e08e0bee-cae4-4fe9-ae7b-9d28851c0503'	System	15 Sep 2020 01:05:09
User entered '14 Sep 2020 21:05'	System	15 Sep 2020 01:05:09

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '14 Sep 2020 15:25'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 2'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:13', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:20', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:23', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'None (0)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered 'No (N)'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-15T21:04:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6867b266-e882-4330-9af2-f0bd2b5270b3' User entered '15 Sep 2020 21:04'	System	16 Sep 2020 01:04:51
	System	16 Sep 2020 01:04:51

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 3'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:40', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:42', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:45', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:48', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:02:54', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered 'None (0)'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:03:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a'	System	17 Sep 2020 01:03:14
User entered 'No (N)'	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-16T21:03:09', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '731d8d63-c530-43ff-ae52-5abb1ae83a5a' User entered '16 Sep 2020 21:03'	System	17 Sep 2020 01:03:14
	System	17 Sep 2020 01:03:14

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 4'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:25', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:27', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:31', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'None (0)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered 'No (N)'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-17T21:02:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1f4d2d55-1d22-4c9b-8597-397cbb9a538c' User entered '17 Sep 2020 21:02'	System	18 Sep 2020 01:02:53
	System	18 Sep 2020 01:02:53

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 5'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:05', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:08', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:13', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'None (0)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:19', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered 'No (N)'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-18T21:03:30', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5ac7dd75-4be2-405f-b862-c6f38227d987' User entered '18 Sep 2020 21:03'	System	19 Sep 2020 01:03:37
	System	19 Sep 2020 01:03:37

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 6'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:31', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:41', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:44', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:46', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered 'None (0)'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:02:54', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581'	System	20 Sep 2020 01:03:04
User entered 'No (N)'	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-19T21:03:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'b756063c-ea97-4a20-b193-48d0404f7581' User entered '19 Sep 2020 21:03'	System	20 Sep 2020 01:03:04
	System	20 Sep 2020 01:03:04

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	14 Sep 2020 15:51:44
User entered 'Day 7'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:04', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:07', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:13', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:16', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:19', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:22', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'None (0)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered 'No (N)'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-09-20T21:04:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6f5ef70f-299e-4582-b6a7-7f088cc9b0a0' User entered '20 Sep 2020 21:04'	System	21 Sep 2020 01:04:41
	System	21 Sep 2020 01:04:41

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:51:44

US3412262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:51:44

US3412262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:22
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:40

US3412262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:22
User entered '21 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:40

US3412262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:22
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:40

US3412262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:22
User entered empty.	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:40

US3412262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:27
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:46:53

US3412262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	25 Sep 2020 12:46:53

US3412262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:41
User entered 'Yes (Y)'		29 Sep 2020 11:14:29

US3412262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:41
User entered '28 Sep 2020'		29 Sep 2020 11:14:29

US3412262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:41
User entered 'Contact Made (CONTACT MADE)'		29 Sep 2020 11:14:29

US3412262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 12:21:41
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 11:14:29

US3412262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:59
User entered 'Yes (Y)'		29 Sep 2020 11:14:13

US3412262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'I'	System	29 Sep 2020 11:14:13

US3412262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:06
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 15:52:46

US3412262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:06
User entered '5 Oct 2020'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 15:52:46

US3412262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:06
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 15:52:46

US3412262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:06
User entered empty.	Mason Urban (b) (4) (b) (4)	05 Oct 2020 15:52:46

US3412262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:10
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 15:52:51

US3412262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	05 Oct 2020 15:52:51

US3412262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:51
User entered 'Yes (Y)'		19 Oct 2020 15:39:57

US3412262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:35:51
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:39:57

US3412262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:51
User entered 'Clinic (Clinic)'		19 Oct 2020 15:39:57

US3412262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered 'VISIT3'	System	19 Oct 2020 15:39:57

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered 'No (N)'		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered empty.	System	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered empty.	System	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered empty.	System	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered empty.	System	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:56
User entered empty.		19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21
User entered empty.	System	19 Oct 2020 15:40:09

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21

US3412262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:21

US3412262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:59
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	21 Oct 2020 16:28:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:40:28

US3412262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:35:59
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	21 Oct 2020 16:28:45
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:40:28

US3412262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:36:07
User entered 'Yes (Y)'		19 Oct 2020 15:40:45

US3412262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:36:07
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:40:45

US3412262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:36:07
User entered '10:40'	(b) (4), (b) (6)	19 Oct 2020 15:40:45

US3412262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '19 Oct 2020 10:40'	System	19 Oct 2020 15:40:45

US3412262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:05:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:36:11
User entered 'Yes (Y)'		19 Oct 2020 15:40:55

US3412262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered '1'	System	19 Oct 2020 15:40:55

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 64'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-19T19:58:02', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f27ec046-cc0f-46a0-bd00-6942f9d3231a'	System	19 Oct 2020 23:58:20
User entered 'No (N)'	System	19 Oct 2020 23:58:20

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-19T19:58:12', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f27ec046-cc0f-46a0-bd00-6942f9d3231a'	System	19 Oct 2020 23:58:20
User entered 'No (N)'	System	19 Oct 2020 23:58:20

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-19T19:58:18', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'f27ec046-cc0f-46a0-bd00-6942f9d3231a' User entered '19 Oct 2020 19:58:18'	System	19 Oct 2020 23:58:20
	System	19 Oct 2020 23:58:20

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 71'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-26T19:48:35', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '01e82861-44d8-4461-a36e-335563d8da5f'	System	26 Oct 2020 23:48:57
User entered 'No (N)'	System	26 Oct 2020 23:48:57

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-26T19:48:42', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '01e82861-44d8-4461-a36e-335563d8da5f'	System	26 Oct 2020 23:48:57
User entered 'No (N)'	System	26 Oct 2020 23:48:57

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-10-26T19:48:54', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '01e82861-44d8-4461-a36e-335563d8da5f' User entered '26 Oct 2020 19:48:54'	System	26 Oct 2020 23:48:57
	System	26 Oct 2020 23:48:57

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 78'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-02T19:46:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '606da070-648c-451f-a56d-b955d3c39902'	System	03 Nov 2020 00:46:50
User entered 'No (N)'	System	03 Nov 2020 00:46:50

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-02T19:46:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '606da070-648c-451f-a56d-b955d3c39902'	System	03 Nov 2020 00:46:50
User entered 'No (N)'	System	03 Nov 2020 00:46:50

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-02T19:46:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '606da070-648c-451f-a56d-b955d3c39902'	System	03 Nov 2020 00:46:50
User entered '02 Nov 2020 19:46:47'	System	03 Nov 2020 00:46:50

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered 'Day 92'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-16T19:42:29', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a07907b5-eeae-4563-b8cf-a838701145f4'	System	17 Nov 2020 00:42:53
User entered 'No (N)'	System	17 Nov 2020 00:42:53

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-16T19:42:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a07907b5-eeae-4563-b8cf-a838701145f4'	System	17 Nov 2020 00:42:53
User entered 'No (N)'	System	17 Nov 2020 00:42:53

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-16T19:42:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'a07907b5-eeae-4563-b8cf-a838701145f4' User entered '16 Nov 2020 19:42:51'	System	17 Nov 2020 00:42:53
	System	17 Nov 2020 00:42:53

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:29:56

US3412262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:04:08
Data entry locked.	System	17 Aug 2020 20:29:56
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:29:56

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-25T12:08:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6332356e-2094-4fd6-8013-4136fff35920'	System	25 Nov 2020 17:08:47
User entered 'No (N)'	System	25 Nov 2020 17:08:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-25T12:08:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6332356e-2094-4fd6-8013-4136fff35920'	System	25 Nov 2020 17:08:47
User entered 'No (N)'	System	25 Nov 2020 17:08:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-11-25T12:08:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6332356e-2094-4fd6-8013-4136fff35920'	System	25 Nov 2020 17:08:47
User entered '25 Nov 2020 12:08:43'	System	25 Nov 2020 17:08:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-02T07:54:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '51213155-3b67-49cf-9d8d-c69fe12b1d7d' User entered 'No (N)'	System	02 Dec 2020 12:54:59
	System	02 Dec 2020 12:54:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-02T07:54:47', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '51213155-3b67-49cf-9d8d-c69fe12b1d7d'	System	02 Dec 2020 12:54:59
User entered 'No (N)'	System	02 Dec 2020 12:54:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-02T07:54:58', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '51213155-3b67-49cf-9d8d-c69fe12b1d7d' User entered '02 Dec 2020 07:54:58'	System	02 Dec 2020 12:54:59
	System	02 Dec 2020 12:54:59

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-09T17:57:24', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '007447e5-258d-4001-8825-86d6757d871c'	System	09 Dec 2020 22:57:39
User entered 'No (N)'	System	09 Dec 2020 22:57:39

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-09T17:57:31', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '007447e5-258d-4001-8825-86d6757d871c'	System	09 Dec 2020 22:57:39
User entered 'No (N)'	System	09 Dec 2020 22:57:39

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-09T17:57:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '007447e5-258d-4001-8825-86d6757d871c' User entered '09 Dec 2020 17:57:37'	System	09 Dec 2020 22:57:39
	System	09 Dec 2020 22:57:39

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-16T02:47:51', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6fc66b0f-34de-465a-9e93-a1b0420c1467'	System	16 Dec 2020 07:48:07
User entered 'No (N)'	System	16 Dec 2020 07:48:07

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-16T02:47:58', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6fc66b0f-34de-465a-9e93-a1b0420c1467'	System	16 Dec 2020 07:48:07
User entered 'No (N)'	System	16 Dec 2020 07:48:07

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-16T02:48:04', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6fc66b0f-34de-465a-9e93-a1b0420c1467' User entered '16 Dec 2020 02:48:04'	System	16 Dec 2020 07:48:07
	System	16 Dec 2020 07:48:07

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-23T20:06:27', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '793a1188-7734-4e63-b0b5-1a8967bd5407'	System	24 Dec 2020 01:06:42
User entered 'No (N)'	System	24 Dec 2020 01:06:42

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-23T20:06:32', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '793a1188-7734-4e63-b0b5-1a8967bd5407'	System	24 Dec 2020 01:06:42
User entered 'No (N)'	System	24 Dec 2020 01:06:42

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-23T20:06:37', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '793a1188-7734-4e63-b0b5-1a8967bd5407' User entered '23 Dec 2020 20:06:37'	System	24 Dec 2020 01:06:42
	System	24 Dec 2020 01:06:42

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-30T20:41:27', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5dbbfeb1-9066-4362-8ea9-8d3137543d61'	System	31 Dec 2020 01:41:54
User entered 'No (N)'	System	31 Dec 2020 01:41:54

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-30T20:41:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5dbbfeb1-9066-4362-8ea9-8d3137543d61'	System	31 Dec 2020 01:41:54
User entered 'No (N)'	System	31 Dec 2020 01:41:54

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2020-12-30T20:41:52', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '5dbbfeb1-9066-4362-8ea9-8d3137543d61' User entered '30 Dec 2020 20:41:52'	System	31 Dec 2020 01:41:54
	System	31 Dec 2020 01:41:54

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-06T12:13:20', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '06ce8bb5-f2c6-42e5-bbbb-5c095dbbbf30'	System	06 Jan 2021 17:13:36
User entered 'No (N)'	System	06 Jan 2021 17:13:36

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-06T12:13:26', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '06ce8bb5-f2c6-42e5-bbbb-5c095dbbbf30'	System	06 Jan 2021 17:13:36
User entered 'No (N)'	System	06 Jan 2021 17:13:36

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-06T12:13:30', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '06ce8bb5-f2c6-42e5-bbbb-5c095dbbbf30' User entered '06 Jan 2021 12:13:30'	System	06 Jan 2021 17:13:36
	System	06 Jan 2021 17:13:36

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-13T22:33:56', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aaef0ed1-36e1-46d4-a995-f3cf6665e019'	System	14 Jan 2021 03:34:10
User entered 'No (N)'	System	14 Jan 2021 03:34:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-13T22:34:01', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aaef0ed1-36e1-46d4-a995-f3cf6665e019'	System	14 Jan 2021 03:34:10
User entered 'No (N)'	System	14 Jan 2021 03:34:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-13T22:34:05', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aaef0ed1-36e1-46d4-a995-f3cf6665e019' User entered '13 Jan 2021 22:34:05'	System	14 Jan 2021 03:34:10
	System	14 Jan 2021 03:34:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-20T10:43:35', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6011f481-0c21-46c4-b935-243020568610'	System	20 Jan 2021 15:43:47
User entered 'No (N)'	System	20 Jan 2021 15:43:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-20T10:43:40', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6011f481-0c21-46c4-b935-243020568610' User entered 'No (N)'	System	20 Jan 2021 15:43:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-20T10:43:44', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6011f481-0c21-46c4-b935-243020568610' User entered '20 Jan 2021 10:43:44'	System	20 Jan 2021 15:43:47
	System	20 Jan 2021 15:43:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-28T12:58:28', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7edb383d-98f3-46fb-b21e-8240bad7e062'	System	28 Jan 2021 17:58:40
User entered 'No (N)'	System	28 Jan 2021 17:58:40

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-28T12:58:34', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7edb383d-98f3-46fb-b21e-8240bad7e062'	System	28 Jan 2021 17:58:40
User entered 'No (N)'	System	28 Jan 2021 17:58:40

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-01-28T12:58:39', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '7edb383d-98f3-46fb-b21e-8240bad7e062'	System	28 Jan 2021 17:58:40
User entered '28 Jan 2021 12:58:39'	System	28 Jan 2021 17:58:40

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-03T09:19:33', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '64bc6c65-db7c-4323-b742-d40e0889f7f8'	System	03 Feb 2021 14:19:45
User entered 'No (N)'	System	03 Feb 2021 14:19:45

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-03T09:19:38', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '64bc6c65-db7c-4323-b742-d40e0889f7f8'	System	03 Feb 2021 14:19:45
User entered 'No (N)'	System	03 Feb 2021 14:19:45

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-03T09:19:43', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '64bc6c65-db7c-4323-b742-d40e0889f7f8'	System	03 Feb 2021 14:19:45
User entered '03 Feb 2021 09:19:43'	System	03 Feb 2021 14:19:45

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-10T09:56:11', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fcf4aed7-f6ea-48ec-99c5-7fb0b354dab8'	System	10 Feb 2021 14:56:27
User entered 'No (N)'	System	10 Feb 2021 14:56:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-10T09:56:17', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fcf4aed7-f6ea-48ec-99c5-7fb0b354dab8'	System	10 Feb 2021 14:56:27
User entered 'No (N)'	System	10 Feb 2021 14:56:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-10T09:56:24', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fcf4aed7-f6ea-48ec-99c5-7fb0b354dab8' User entered '10 Feb 2021 09:56:24'	System	10 Feb 2021 14:56:27
	System	10 Feb 2021 14:56:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-18T12:36:10', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0560fcb6-6a3d-4324-a21b-6509b97eb0ab'	System	18 Feb 2021 17:36:27
User entered 'No (N)'	System	18 Feb 2021 17:36:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-18T12:36:15', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0560fcb6-6a3d-4324-a21b-6509b97eb0ab'	System	18 Feb 2021 17:36:27
User entered 'No (N)'	System	18 Feb 2021 17:36:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-18T12:36:24', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '0560fcb6-6a3d-4324-a21b-6509b97eb0ab' User entered '18 Feb 2021 12:36:24'	System	18 Feb 2021 17:36:27
	System	18 Feb 2021 17:36:27

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-24T07:40:05-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6c468b56-3e85-46e7-b558-c4817abaefc8'	System	24 Feb 2021 12:40:17
User entered 'No (N)'	System	24 Feb 2021 12:40:17

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-24T07:40:10-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6c468b56-3e85-46e7-b558-c4817abaefc8'	System	24 Feb 2021 12:40:17
User entered 'No (N)'	System	24 Feb 2021 12:40:17

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-02-24T07:40:15-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6c468b56-3e85-46e7-b558-c4817abaefc8'	System	24 Feb 2021 12:40:17
User entered '24 Feb 2021 12:40:15'	System	24 Feb 2021 12:40:17

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-04T08:46:57-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'bf542a8e-cc75-4a51-8e4a-cafc491ab04f'	System	04 Mar 2021 13:47:10
User entered 'No (N)'	System	04 Mar 2021 13:47:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-04T08:47:02-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'bf542a8e-cc75-4a51-8e4a-cafc491ab04f'	System	04 Mar 2021 13:47:10
User entered 'No (N)'	System	04 Mar 2021 13:47:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-04T08:47:07-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'bf542a8e-cc75-4a51-8e4a-cafc491ab04f' User entered '04 Mar 2021 08:47:07'	System	04 Mar 2021 13:47:10
	System	04 Mar 2021 13:47:10

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-10T09:02:52-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'eb72d1ab-c756-4ed9-9726-056cd32267bf'	System	10 Mar 2021 14:03:06
User entered 'No (N)'	System	10 Mar 2021 14:03:06

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-10T09:02:57-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'eb72d1ab-c756-4ed9-9726-056cd32267bf' User entered 'No (N)'	System	10 Mar 2021 14:03:06
	System	10 Mar 2021 14:03:06

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-10T09:03:02-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'eb72d1ab-c756-4ed9-9726-056cd32267bf' User entered '10 Mar 2021 09:03:02'	System	10 Mar 2021 14:03:06
	System	10 Mar 2021 14:03:06

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-17T11:35:05-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aca61d24-e7d7-42bf-8f72-340a11d21aa8'	System	17 Mar 2021 15:35:23
User entered 'No (N)'	System	17 Mar 2021 15:35:23

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-17T11:35:11-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aca61d24-e7d7-42bf-8f72-340a11d21aa8'	System	17 Mar 2021 15:35:23
User entered 'No (N)'	System	17 Mar 2021 15:35:23

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-17T11:35:15-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'aca61d24-e7d7-42bf-8f72-340a11d21aa8' User entered '17 Mar 2021 11:35:15'	System	17 Mar 2021 15:35:23
	System	17 Mar 2021 15:35:23

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-24T09:05:20-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e017bd7-98ab-4625-8971-26d545b0d71c'	System	24 Mar 2021 13:05:38
User entered 'No (N)'	System	24 Mar 2021 13:05:38

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-24T09:05:25-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e017bd7-98ab-4625-8971-26d545b0d71c'	System	24 Mar 2021 13:05:38
User entered 'No (N)'	System	24 Mar 2021 13:05:38

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-24T09:05:30-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '6e017bd7-98ab-4625-8971-26d545b0d71c'	System	24 Mar 2021 13:05:38
User entered '24 Mar 2021 09:05:30'	System	24 Mar 2021 13:05:38

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-31T13:27:44-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '209ab128-d0f2-4495-92f2-e380a6ae376a'	System	31 Mar 2021 17:29:44
User entered 'No (N)'	System	31 Mar 2021 17:29:44

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-31T13:27:49-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '209ab128-d0f2-4495-92f2-e380a6ae376a'	System	31 Mar 2021 17:29:44
User entered 'No (N)'	System	31 Mar 2021 17:29:44

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-31T13:27:57-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '209ab128-d0f2-4495-92f2-e380a6ae376a' User entered '31 Mar 2021 13:27:57'	System	31 Mar 2021 17:29:44
	System	31 Mar 2021 17:29:44

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-07T13:44:03-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1c479098-22d1-4520-a5dc-87d79a337818'	System	07 Apr 2021 17:44:18
User entered 'No (N)'	System	07 Apr 2021 17:44:18

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-07T13:44:09-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1c479098-22d1-4520-a5dc-87d79a337818'	System	07 Apr 2021 17:44:18
User entered 'No (N)'	System	07 Apr 2021 17:44:18

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-07T13:44:13-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '1c479098-22d1-4520-a5dc-87d79a337818'	System	07 Apr 2021 17:44:18
User entered '07 Apr 2021 13:44:13'	System	07 Apr 2021 17:44:18

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-14T12:55:12-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3a03f83f-e28a-489b-8a57-8915882b610d'	System	14 Apr 2021 18:16:21
User entered 'No (N)'	System	14 Apr 2021 18:16:21

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-14T12:55:17-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3a03f83f-e28a-489b-8a57-8915882b610d'	System	14 Apr 2021 18:16:21
User entered 'No (N)'	System	14 Apr 2021 18:16:21

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-14T12:55:21-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '3a03f83f-e28a-489b-8a57-8915882b610d'	System	14 Apr 2021 18:16:21
User entered '14 Apr 2021 12:55:21'	System	14 Apr 2021 18:16:21

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-21T06:05:36-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fb9762e0-e57c-4d92-b918-3a81d5946238'	System	21 Apr 2021 10:05:47
User entered 'No (N)'	System	21 Apr 2021 10:05:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-21T06:05:40-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fb9762e0-e57c-4d92-b918-3a81d5946238'	System	21 Apr 2021 10:05:47
User entered 'No (N)'	System	21 Apr 2021 10:05:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-21T06:05:44-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: 'fb9762e0-e57c-4d92-b918-3a81d5946238' User entered '21 Apr 2021 06:05:44'	System	21 Apr 2021 10:05:47
	System	21 Apr 2021 10:05:47

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:01:33-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered 'Yes (Y)'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Have you been exposed to someone with 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:01:41-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered 'No (N)'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:01:52-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered 'No (N)'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:02:09-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered 'Yes (Y)'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

Please 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 (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:02:21-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-04-28T09:02:36-04:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '9ec13738-74c5-4090-aef1-789677cb4898'	System	29 Apr 2021 00:12:26
User entered '28 Apr 2021 09:02:36'	System	29 Apr 2021 00:12:26

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:33:20

US3412262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:33:20
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:33:20

US3412262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:47

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)	26 Apr 2021 00:44:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-04T08:47:20-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '4a11082b-7dc7-4375-b815-d04897376b07'	System	04 Mar 2021 13:47:37
User entered 'No (N)'	System	04 Mar 2021 13:47:37

US3412262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:44:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B4365388-EB97-40A6-BB79-5496EB50B17E)', Time: '2021-03-04T08:47:32-05:00', User OID: 'PatientReportedOutcome (US3412262)', ODM File OID: '4a11082b-7dc7-4375-b815-d04897376b07'	System	04 Mar 2021 13:47:37
User entered '04 Mar 2021 08:47:32'	System	04 Mar 2021 13:47:37

US3412262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:39:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:21
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	17 Nov 2020 22:52:39

US3412262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:39:06
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 11:29:43
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Scheduled in Clinical Conductor for 16 NOV 2020, completed 17 NOV 2020 because patient was not reached on 16 NOV 2020' (Site from System).	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:48:00
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:10:21
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Nov 2020 22:52:39
User entered '17 Nov 2020'	Mason Urban (b) (4) (b) (4)	17 Nov 2020 22:52:39

US3412262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:39:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	17 Nov 2020 22:52:39

US3412262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:39:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:21
User entered empty.	Mason Urban (b) (4) (b) (4)	17 Nov 2020 22:52:39

US3412262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:39:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:25
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	17 Nov 2020 22:52:44

US3412262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:20
User entered 'I'	System	17 Nov 2020 22:52:44

US3412262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:30
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	21 Dec 2020 16:24:58

US3412262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:30
User entered '21 Dec 2020'	Mason Urban (b) (4) (b) (4)	21 Dec 2020 16:24:58

US3412262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:30
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	21 Dec 2020 16:24:58

US3412262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:30
User entered empty.	Mason Urban (b) (4) (b) (4)	21 Dec 2020 16:24:58

US3412262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:35
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	21 Dec 2020 16:25:27

US3412262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User entered 'I'	System	21 Dec 2020 16:25:27

US3412262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:00:28
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:51:05

US3412262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:00:28
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		01 Feb 2021 15:06:47
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'SUBJECT WAS JUST HERE ON 15-JAN-2021 FOR PARTICIPANT DECISION CLINIC VISIT AND SAFETY CALL WAS SCHEDULED FOR 19-JAN-2021 AT NOON' (Site from System).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:05:49
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	19 Jan 2021 16:51:05
User entered '19 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:51:05

US3412262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:00:28
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:51:05

US3412262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:00:28
User entered empty.	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:51:05

US3412262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:00:38
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:59:46

US3412262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User entered '1'	System	19 Jan 2021 16:59:46

US3412262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 12:51:52
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	10 Feb 2021 17:07:48

US3412262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 12:51:52
User entered '10 Feb 2021'	Mason Urban (b) (4) (b) (4)	10 Feb 2021 17:07:48

US3412262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 12:51:52
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	10 Feb 2021 17:07:48

US3412262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 12:51:52
User entered empty.	Mason Urban (b) (4) (b) (4)	10 Feb 2021 17:07:48

US3412262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 12:51:58
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	10 Feb 2021 17:08:48

US3412262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:36:05
User entered '1'	System	10 Feb 2021 17:08:48

US3412262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:07:50
User entered 'Yes (Y)'		22 Mar 2021 17:10:38

US3412262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:07:50
User entered '22 Mar 2021'		22 Mar 2021 17:10:38

US3412262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[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 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:07:50
User entered 'Clinic (Clinic)'		22 Mar 2021 17:10:38

US3412262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered 'VISIT4'	System	22 Mar 2021 17:10:38

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered 'No (N)'		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.		31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.	(b) (4)	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:08:02
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered empty.	System	31 Mar 2021 20:08:23

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51

US3412262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51

US3412262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:14
User entered 'No (N)'		22 Mar 2021 17:10:44

US3412262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:08:14
User entered empty.		22 Mar 2021 17:10:44

US3412262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
DataPoint Verified.		16 Apr 2021 16:55:01
User closed query 'per source sample was collected 22 Mar 2021 at 09:56? Please confirm and update accordingly' (Site from CRA).		16 Apr 2021 16:54:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
Query 'per source sample was collected 22 Mar 2021 at 09:56? Please confirm and update accordingly' answered with 'this has been updated with the date' (Site from CRA).	(b) (4)	
	Steven Anderson (b) (4)	16 Apr 2021 12:51:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Apr 2021 12:51:05
	(b) (4)	
User opened query 'per source sample was collected 22 Mar 2021 at 09:56? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:09:53
User entered 'No (N)'		22 Mar 2021 17:11:15

US3412262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
DataPoint Verified.	(b) (4)	16 Apr 2021 16:55:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	16 Apr 2021 12:51:05
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:11:15

US3412262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:55:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Apr 2021 13:34:26
User entered '09:56' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Apr 2021 13:34:26
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Apr 2021 12:51:05
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:11:15

US3412262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '22 Mar 2021 09:56'	System	16 Apr 2021 13:34:26
User entered empty.	System	22 Mar 2021 17:11:15

US3412262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:10:06
User entered 'Yes (Y)'		22 Mar 2021 17:11:21

US3412262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:51
User entered '1'	System	22 Mar 2021 17:11:21

US3412262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:10:53
User entered 'Yes (Y)'		12 Apr 2021 17:11:54

US3412262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:10:53
User entered '12 Apr 2021'		12 Apr 2021 17:11:54

US3412262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:10:53
User entered 'Contact Made (CONTACT MADE)'		12 Apr 2021 17:11:54

US3412262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4)	15 Apr 2021 21:10:53
User entered 'Left VM on 12 APR 2021. Patient called back same day.'	(b) (4), (b) (6)	12 Apr 2021 17:11:54

US3412262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:11:06
User entered 'Yes (Y)'		12 Apr 2021 17:11:58

US3412262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 17:11:58

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:01:47
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:27

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:01:47
User entered '15 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:27

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:01:47
User entered 'Clinic (Clinic)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:27

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:45:27

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered '15 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 12:04:26
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:55:08

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		10 Apr 2021 06:18:18
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:04:28
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:04:26
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:40:01
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:55:08

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered '15 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 12:07:46
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 12:07:46
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:28
User entered 'No (N)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User entered empty.	System	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:35:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User entered empty.	System	19 Jan 2021 16:45:46

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:47
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:58

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:47
User entered '15 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:58

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:47
User entered '13:22'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:45:58

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User entered '15 Jan 2021 13:22'	System	19 Jan 2021 16:45:58

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:58
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:46:10

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:58
User entered '15 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:46:10

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:58
User entered '13:24'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 16:46:10

US3412262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:47

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:12
User entered '15 Jan 2021 13:24'	System	19 Jan 2021 16:46:10

US3412262

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:35:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:28
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:09:59
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:37:50
Signature has been broken.		28 Apr 2021 17:37:50
User entered 'Yes (Y)' reason for change: New Information		28 Apr 2021 17:37:50
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:40:44
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:47:35

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:19
User entered 'USA-US061-2021-mRNA-1273-P301000020'	System	28 Apr 2021 19:00:14
User entered 'New'	(b) (4), (b) (6)	28 Apr 2021 19:00:14

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Apr 2021 19:28:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:28:34
Data point term sent to Coder	System	28 Apr 2021 17:43:37
User entered 'Worsening L hip OA'	(b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '1'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '24 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '1'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '1'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'Subject notified out site at 1200 on 28 APR 2021 of worsening L hip OA. Subject's L hip OA worsened 01 APR 2021 and on 21 APR 2021 subject was admitted for L hip replacement surgery at IU health Saxony. Subject was discharged on 24 APR 2021 and was sent to rehab at Allisonville Meadows in Fishers, Indiana. Subject is currently still in rehab.'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:43:21

US3412262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:43:21

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:35:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:28
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:42:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:20
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:23:55

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:18:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:18:47
Data point term sent to Coder	System	24 Aug 2020 16:31:11
User entered 'MELOXICAM'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'HIP PAIN'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered '15'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'UN Feb 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:14:17
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 16:31:08

US3412262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:35:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:42:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:40:33
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	25 Sep 2020 12:47:55

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'USA-US061-2021-MRNA-1273-P301000020'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Yes (Y)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Yes (Y)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Richard'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Powell'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'OH'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'US'	(b) (4) System	28 Apr 2021 19:00:35

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 19:00:35

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'USA-US061-2021-MRNA-1273-P301000020'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Yes (Y)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Yes (Y)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'No (N)'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Richard'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'Powell'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:28
User entered 'OH'	System	28 Apr 2021 19:00:14

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'US'	(b) (4) System	28 Apr 2021 19:00:35

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 19:00:35

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:47

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered '28/Apr/2021 14:00'	(b) (4) System	28 Apr 2021 19:00:35

US3412262

Folder: SAE USA-US061-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:47

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.	Richard Powell (b) (4)	28 Apr 2021 23:57:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:00:35